Application Proof of

Shandong Boan Biotechnology Co., Ltd.
(山东博安生物技术股份有限公司)

(the "**Company**")

(A joint stock company incorporated in the People's Republic of China with limited liability)

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Shandong Boan Biotechnology Co., Ltd.
山东博安生物技术股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

[REDACTED]

Number of [REDACTED] under the [REDACTED]	**:**	**[REDACTED] H Shares (subject to the [REDACTED])**
Number of [REDACTED]	**:**	**[REDACTED] H Shares (subject to reallocation)**
Number of [REDACTED]	**:**	**[REDACTED] H Shares (including [REDACTED] [REDACTED] under the [REDACTED], subject to reallocation and the [REDACTED])**
Maximum [REDACTED]	**:**	**HK$[REDACTED] per H Share, plus brokerage of 1.0%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.005% and AFRC transaction levy of 0.00015% (payable in full on application in Hong Kong dollars and subject to refund)**
Nominal Value	**:**	**RMB1.00 per H Share**
[REDACTED]	**:**	**[REDACTED]**

***Joint Sponsors and* [REDACTED]**

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We are incorporated, and a majority of our business is located, in the PRC. Potential investors should be aware of the differences in the legal, economic and financial systems between the PRC and Hong Kong and that there are different risk factors relating to investment in PRC-incorporated businesses. Potential investors should also be aware that the regulatory framework in the PRC is different from the regulatory framework in Hong Kong and should take into consideration the different market nature of the H Shares. Such differences and risk factors are set out in the sections headed "Risk Factors" and "Regulatory Overview" in this document and "Appendix IV — Summary of Principal Legal and Regulatory Provisions" and "Appendix V — Summary of Articles of Association" to this document.

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IMPORTANT

[REDACTED]

IMPORTANT

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[REDACTED]

EXPECTED TIMETABLE[1]

[REDACTED]

EXPECTED TIMETABLE[1]

[REDACTED]

EXPECTED TIMETABLE[1]

[REDACTED]

EXPECTED TIMETABLE[1]

[REDACTED]

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CONTENTS

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to invest in the [**REDACTED**]. *There are risks associated with any investment. Some of the particular risks in investing in the* [**REDACTED**] *are set out in the section headed "Risk Factors" in this document. You should read that section carefully before you decide to invest in the* [**REDACTED**].

OVERVIEW

We are an integrated biopharmaceutical company committed to developing, manufacturing and commercializing high quality biologics across various therapeutic areas in China and overseas. Since our inception in 2013, we have fostered multiple key elements we believe will help us capture the strong market opportunity in biologics, including:

(i) a management team with extensive industry experience and market insight that has pushed forward our strategic plans including successfully bringing Boyounuo® (博优诺®) (BA1101) ("**Boyounuo® (BA1101)**") to market in China in May 2021;

(ii) a robust and risk-balanced portfolio, which brings us clear short-term commercial visibility and allows us to pursue long-term sustainable growth;

(iii) an integrated biopharmaceutical platform; and

(iv) collaboration with various resourceful business partners, laying the foundation for our strong commercialization capability.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET THE CORE PRODUCTS AS REQUIRED UNDER RULE 18A.05 OF THE LISTING RULES, OR ANY OF OUR DRUG CANDIDATES.

We focus our platform, people and partnerships on offering access to innovative biologics as well as affordable biosimilars. To date, we have successfully commercialized Boyounuo® (BA1101) and recorded a revenue of RMB158.7 million in about eight months in 2021 and RMB220.7 million from its sales for the six months ended June 30, 2022, which demonstrated our capability to bring our biologics portfolio to market. The [**REDACTED**] of our Company constitutes a [**REDACTED**] of our Company from Luye Pharma.

Our portfolio brings us clear short-term commercial visibility and allows us to pursue long-term sustainable growth. Our portfolio comprised three Core Products, one commercialized product and 10 other drug candidates as of the Latest Practicable Date. Our drug candidates in development include both innovative and biosimilar drugs. As of the Latest Practicable Date, we had launched a biosimilar product commercially, namely Boyounuo® (BA1101), and we were developing eight innovative antibody drug candidates and five biosimilar candidates in our pipeline, 11 of which had entered or completed clinical trials or received the IND approvals from the CDE, comprising (i) one drug candidate with biologic license application (the "**BLA**") approved, (ii) three in Phase 3 clinical trial, (iii) one in Phase 2 clinical trial, (iv) four in Phase 1 clinical trial, and (v) two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU.

SUMMARY

The following table summarizes our Commercialized Product and drug candidate pipeline under development in China and worldwide across various therapeutic areas as of the Latest Practicable Date:

	Therapeutic area	Product (reference drug)	Target	Indication	Commercial rights	Clinical trial region	Pre-clinical	IND	Phase 1	Phase 2[10]	Phase 3	BLA filed	BLA approved
Innovative Antibody Portfolio	Infectious Disease	★ LY-CovMab[1]	SARS-CoV-2 spike protein	COVID-19	Worldwide	China							
		BA-CovMab	SARS-CoV-2 spike protein	COVID-19	Worldwide	China							
	Oncology	BA1105	Claudin 18.2 (ADCC)	Advanced gastric cancer, metastatic pancreatic cancer, and adenocarcinoma of the esophagogastric junction	Worldwide	China							
		BA1301	Claudin 18.2 ADC	Gastric cancer, pancreatic cancer, and esophageal cancer	Worldwide	China							
		BA1201	PD-L1/TGF-β	SCLC, NSCLC, cervical cancer, urothelial carcinoma, and advanced gastrointestinal tumors	Worldwide	China							
		BA1202	CEA/CD3	CRC, pancreatic duct adenocarcinoma, etc.	Worldwide	China							
		BA1106	CD25	Solid tumors	Worldwide	China							
	Autoimmunity	BA2101	IL4R	Atopic dermatitis, asthma, sinusitis, pruritus, urticaria, etc.	Worldwide	China							
Biosimilar Portfolio	Oncology	Boyounuo®* (BA1101, Avastin® biosimilar)[2]	VEGF	mCRC, advanced metastatic or recurrent NSCLC, recurrent glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer, and cervical cancer	Worldwide	China							
		★ BA1102 (Xgeva® biosimilar)[3]	RANKL	Bone metastases from solid tumors, and GCTB	Worldwide	China							
						Overseas							
		BA1104 (Opdivo® biosimilar)[4]	PD-1	Melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma	Worldwide	China							
						Overseas							
	Metabolism	★ BA6101 (Prolia® biosimilar)[5]	RANKL	Osteoporosis[6]	Worldwide	China							
						Overseas							
		BA5101 (Trulicity® biosimilar)[7]	GLP-1	Type 2 diabetes	Worldwide	China[11]							
						Overseas							
	Ophthalmology	BA9101 (Eylea® biosimilar)[8] [9]	VEGF	wAMD, RVO, DME, and DR	Worldwide[9]	China							
						Overseas							

Notes:

★ Denotes our Core Products.

* Denotes our Commercialized Product.

(1) We expect to submit the BLA of LY-CovMab in 2024. For more details, see "Business — Our innovative antibody portfolio — Our Core Product: LY-CovMab".

(2) The generic name of Boyounuo® (BA1101) is bevacizumab. We entered into an agreement with AstraZeneca (Wuxi) Trading Co., Ltd.* (阿斯利康(無錫)貿易有限公司) ("**AstraZeneca China**") with respect to Boyounuo® (BA1101) on May 26, 2021, as amended by a supplemental agreement dated March 7, 2022, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. For more details, see "Business — Our biosimilar portfolio — Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®)".

(3) The generic name of BA1102 is denosumab. We expect to submit the BLA of BA1102 in the first quarter of 2023 in China. The results of the Phase 1 clinical trial in the EU are expected to become available in the second half of 2023. Although BA1102 and BA6101 contain the same active agent, denosumab, they were developed as separate product candidates rather than expansion of indications of each other. The generic name of BA1102 is denosumab. For more details, see "Business — Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)".

(4) The generic name of BA1104 is nivolumab. For more details, see "Business — Our biosimilar portfolio — BA1104 (a biosimilar to Opdivo®)".

(5) The generic name of BA6101 is denosumab. We received the regulatory approval to commence commercialization in November 2022 in China. It is also currently under Phase 1 clinical trial in the EU, the results of which are expected to become available in the second half of 2023. For more details, see "Business — Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)".

(6) Treatments of various osteoporosis consist of (i) treatment of postmenopausal women with osteoporosis at high risk for fracture, (ii) treatment to increase bone mass in men with osteoporosis at high risk for fracture, (iii) treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, (iv) treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and (v) treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

(7) The generic name of BA5101 is dulaglutide. For more details, see "Business — Our biosimilar portfolio — BA5101 (a biosimilar to Trulicity®)".

(8) The generic name of BA9101 is aflibercept. We expect to submit the BLA of BA9101 in the first half of 2024 in China. For more details, see "Business — Our biosimilar portfolio — BA9101 aflibercept intraocular injection (a biosimilar to Eylea®)".

(9) We entered into an agreement with OcuMension Therapeutics (Zhejiang) Co., Ltd.* (歐康維視(浙江)醫藥有限公司) ("**OcuMension**") on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, pursuant to which we are responsible for conducting certain initial stages of the Phase 3 clinical trial and commercial production as well as submitting the BLA of BA9101 and OcuMension is responsible for completing the rest of Phase 3 clinical trial and promoting and commercializing BA9101 in China. The term of the agreement ends on the tenth anniversary following the date of first delivery of BA9101 after marketing approval has been obtained. For more details, see "Business — Commercialization, sales, marketing and distribution — R&D partner and promoter".

(10) In the PRC, the NMPA has issued a number of guidelines encouraging biosimilar research and development, including the Biosimilar Guidelines, which set out the regulatory framework for registering and evaluating new biosimilar candidates. In general, the NMPA requires that biosimilars match the relevant reference drugs in terms of indications, usage guidelines and safety information. In addition, the biosimilar approval pathway is established based on the scientific objective of proving that there are no clinically-meaningful differences in the safety and efficacy of biosimilars when compared to the reference drug. Based on this principle, there is generally no need to conduct a Phase 2 clinical trial for biosimilars since the proper dose assuring safety and efficacy has already been determined for the reference product.

BUSINESS MODEL

We independently developed all of our portfolio in-house, which focuses on popular key therapeutic areas including oncology, metabolism, autoimmunity and ophthalmology, which entail significant unmet market demand and potential in China and globally due to their immense market sizes. The size of global and China patient groups with medical demand in key therapeutic areas of oncology, metabolism, autoimmunity and ophthalmology, has exceeded 2 billion and over 250 million of patients, respectively, in 2021. The global drug market size of these key therapeutic areas is also immense and growing steadily, reaching US$181.7 billion, US$239.5 billion, US$127.7 billion and US$36.0 billion, respectively, for 2021, and is expected to increase to US$484.5 billion, US$359.8 billion, US$176.0 billion and US$73.7 billion, respectively, for 2030, representing a respective CAGR of 11.5%, 4.6%, 3.6% and 8.3% between 2021 and 2030, according to the Frost & Sullivan Report. Similarly, in China the drug market size of the aforementioned key therapeutic areas was RMB231.1 billion, RMB99.9 billion, RMB19.3 billion and RMB20.4 billion, respectively, for 2021, and is expected to increase to RMB651.3 billion, RMB188.5 billion, RMB148.8 billion and RMB99.2 billion, respectively, for 2030, representing a respective CAGR of 12.2%, 7.3%, 25.5% and 19.2% between 2021 and 2030, according to the Frost & Sullivan Report.

We boast our integrated biopharmaceutical platform with proprietary R&D technology. Our integrated platform and deep experience and capabilities built thereon extend to the entire biologics value chain and have provided us with substantial control over quality and resource allocation. Furthermore, we established proprietary technology platforms which we believe provide us with great technological support. Our R&D teams based in Yantai and Nanjing in China and Boston in the United States have rich experience and strong track records in drug discovery and development, including having developed extensive experience in areas of antibody discovery, cell line development, upstream and downstream process development, analytical and bio-analytical method development, technology transfer, pilot and commercial scale production.

We have strong CMC capability which is the backbone to the high quality and cost efficiencies we have maintained throughout the process of our drug development and commercial production, especially in cell line development, upstream and downstream process development, analytical and bio-analytical method development as well as technology transfer. In addition, we have a sizable pilot and commercial production site located in Yantai, China (the "**Yantai Site**") which has a total GFA of approximately 33,504.1 sq.m. and houses a number of production lines with a capacity of 1,700L for pilot production and 8,000L for commercial production, as well as two formulation filling lines for both pilot and commercial production, consisting of (i) the vial filling formulation line with a designed production capacity of 2.5 million vials per annum, and (ii) the pre-filled product formulation line of 3.5 million pre-filled syringes per annum.

Our collaboration with various resourceful business partners lays the foundation for our strong commercialization capability. As of June 30, 2022, we had an extensive distribution network of 160 distributors, penetrating selected regions and reaching more than 1,100 target hospitals and institutions in China. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China. We also collaborate with experienced third-party promoters which effectively publicize and

maximize the market potential of our products by academic promotion such as visiting hospitals, organizing meetings and inviting experts with deep clinical experience to share knowhow or experience, organizing meetings and inviting leading healthcare experts to consult their views on product proposition and strategies and policy changes, collecting market intelligence. Third-party promoters also help on collecting market intelligence, conducting business-supporting matters including tracking shipment, inventory verification and collecting accounts receivable, as well as the formulation and implementation of monthly promotion plans. There is no overlapping role between the third-party promoters and distributors as promoters act as agents to promote our products and, unlike distributors, they do not buy or sell our products. On May 26, 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, regarding the promotion rights to Boyounuo® (BA1101) for a term of five years, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. On October 28, 2020 we entered into an agreement with OcuMension, as amended by a supplemental agreement dated May 31, 2021, regarding the product development cooperation and promotion and commercialization of BA9101 in China for a term of 10 years, under which we granted OcuMension certain exclusive rights to promote and commercialize BA9101 in China. Our strong commercialization capability is further bolstered by a dedicated in-house sales and marketing team with extensive industry experience.

OUR CORE PRODUCTS AND COMMERCIALIZED PRODUCT

Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)

We are developing BA1102 as an Xgeva® (denosumab) biosimilar under the name of Denosumab Injection. Xgeva® (denosumab as its generic name) is primarily used to treat patients with skeletal-related events caused by multiple myeloma and bone metastases from solid tumors as well as GCTB that is unresectable or where surgical resection is likely to result in severe morbidity. Xgeva® is 120 mg of denosumab. We began developing BA1102 in July 2015 and are conducting the Phase 3 clinical trial for bone metastases from solid tumors in China. We expect to complete the Phase 3 clinical trial and to file a BLA with the NMPA in the first quarter of 2023 for the treatment of bone metastases from solid tumors and GCTB, which are the same indications as those approved for Xgeva® in China. We plan to commercialize BA1102 as an affordable alternative to Xgeva® primarily in China, where there is a significant underserved population of patients with bone metastases from solid tumors and GCTB.

Because BA1102 and BA6101 contain the same active agent, denosumab, and have the same mechanism of action (but in a different dose range), we communicated the development strategies of BA1102 and BA6101 with the EMA in April 2019 and with the FDA in October 2019. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phases 1 and 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®. BA1102 is in the stage of Phase 1 clinical trial in the EU, by virtue of the clinical trial we are conducting for BA6101.

In recent years, the morbidity and mortality rates of malignant tumors have continued to rise in China. Bones are the most common site of advanced tumor metastases. Skeletal-related events ("**SRE**") caused by bone metastases not only lead to reduced physical function and quality of life in patients, but also lead to an increased risk of death. With the continuous improvement of anti-cancer treatment methods, the survival time of patients with advanced cancer continues to increase, and the risk of bone metastases and other skeletal complications also increases significantly. Bone metastasis occurs when cancer cells spread from their original site to a bone. The incidence of bone metastases in advanced malignant tumors is as high as 30%-75%. Nearly all types of cancer can metastasize to the bones. Common tumors prone to bone metastases include solid tumors such as breast cancer (65%-75%), prostate cancer (65%-75%), thyroid cancer (60%), lung cancer (30%-40%), kidney cancer (20%-25%) and malignant melanoma (14%-45%), which provide a wide patient base for denosumab. Global bone metastasis drug market size increased from US$11.7 billion in 2017 to US$16.0 billion in 2021, with a CAGR of 8.2%, and is expected to continue to increase to US$32.3 billion in 2030, with a CAGR of 8.1% from 2021 to 2030. China bone metastasis drug market size increased from RMB7.5 billion in 2017 to RMB12.0 billion in 2021, with a CAGR of 12.5%, and is expected to continue to increase to RMB29.8 billion in 2030, with a CAGR of 10.7% from 2021 to 2030. According to the label of denosumab, three clinical trials were conducted to test the efficacy and safety of the drug, targeting bone metastasis in breast cancer, NSCLC and prostate cancer respectively. According to the National Comprehensive Cancer Network ("**NCCN**") guideline, denosumab is mostly of category 1 when treating bone metastasis of different types of primary cancer. Category 1 recommendation represents the highest level of recommendation in the guideline due to consensus on evidence. For NCCN guidelines, the recommendation categories are Category 1, Category 2A, Category 2B and Category 3, where Category 1 means that there is uniform NCCN consensus that the intervention is appropriate based upon high-level evidence.

According to the Frost & Sullivan Report, GCTBs are intermediate malignant bone tumors with high local infiltration ability, which accounts for approximately 5% of all primary bone tumors. More than half of these lesions occur in the third and fourth decades of life. The global incidence of GCTB increased from 11.1 thousand in 2017 to 11.7 thousand in 2021, with a CAGR of 1.4%. It is expected to increase to 13.1 thousand in 2030, with a CAGR of 1.2% from 2021 to 2030. In China, the incidence of GCTB increased from 2.1 thousand in 2017 to 2.1 thousand in 2021, with a CAGR of 0.7%. It is expected to increase to 2.2 thousand in 2030, with a CAGR of 0.6% from 2021 to 2030. Global GCTB drug market size increased from US$90.3 billion in 2017 to US$125.2 billion in 2021, with a CAGR of 8.5%, and is expected to continue to increase to US$199.4 billion in 2030, with a CAGR of 5.3% from 2021 to 2030. China GCTB drug market size increased from RMB16.5 billion in 2017 to RMB19.6 billion in 2021, with a CAGR of 4.5%, and is expected to continue to increase to RMB38.6 billion in 2030, with a CAGR of 7.8% from 2021 to 2030. Xgeva® (denosumab) has been included in the 2020 Chinese Society of Clinical Oncology ("**CSCO**") guideline, making it the first targeted pharmacological treatment of GCTB that was included in the guideline. Xgeva® is class I recommendation for the treatment of unresectable GCTB and class II recommendation for pre-surgical treatment of resectable GCTB. Class I recommendation means evidence and/or general agreement that a given treatment or procedure is beneficial, useful and effective. Class II recommendation means conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.

For more details, see "Business — Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)".

Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)

We developed BA6101 as a Prolia® (denosumab) biosimilar. Prolia® (denosumab as its generic name) is primarily used for the treatment of postmenopausal women with osteoporosis at high risk for fracture, treatment to increase bone mass in men with osteoporosis at high risk for fracture, treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Prolia® is 60 mg of denosumab. We began developing BA6101 in November 2014 and have completed the Phase 3 clinical trial for treating postmenopausal women with osteoporosis at high risk for fracture and have submitted the BLA to the NMPA afterwards. The NMPA has accepted our BLA in October 2021. We received the regulatory approval to commence commercialization of BA6101 in November 2022 in China. In addition, the FDA and the Paul-Ehrlich-Institut in Germany ("**PEI**") have approved our IND application and Clinical Trial Application ("**CTA**") in June 2020 and October 2020, respectively, and we are conducting Phase 1 clinical trial in the EU.

According to the Frost & Sullivan Report, based on a comprehensive systemic review and meta-analysis published in 2021, the overall global prevalence of osteoporosis in the elderly women was 35.3% and in the elderly men was 12.5%. The prevalence of osteoporosis in Asia, Europe, and the United States was 24.3%, 16.7%, and 11.5%, respectively, with the highest prevalence in Asia. The world's aging population is experiencing growth in terms of both number and proportion. According to data from the World Bank, the global population aged over 65 years increased from 650.0 million (8.7% of the total population) in 2017 to 748.1 million (9.6% of the total population) in 2021, and is expected to reach approximately 990.5 million (11.7% of the total population) in 2030. Declining fertility and increasing longevity are the key drivers of population aging globally. Global osteoporosis drug market size increased from US$13.2 billion in 2017 to US$16.8 billion in 2021, with a CAGR of 6.2%, and is expected to continue to increase to US$27.6 billion in 2030, with a CAGR of 5.7% from 2021 to 2030.

According to the China Osteoporosis Prevalence Study conducted between 2017 and 2018 and published in 2021, 5.0% of men and 20.6% of women aged 40 years or above had osteoporosis in China. Osteoporosis is a common and preventable disorder that predisposes an individual to an increased risk of fracture, a major cause of disability in older adults. The most common locations for osteoporosis-related fractures are in the hip, spine, and wrist, and serious hip, spine, and wrist fractures often require surgical intervention, which results in a decline in health-related quality of life. Osteoporosis increases with age. According to the Frost & Sullivan Report, the population of the elderly over 65 years old in China increased from 158.3 million (11.4% of the total population) in 2017 to 200.6 million (14.2% of the total population) in 2021, and is expected to reach approximately 317.6 million (22.0% of the total population) by 2030. China osteoporosis drug market size increased from RMB19.4 billion in 2017 to RMB27.6 billion in 2021, with a CAGR of 9.3%, and is expected to continue to increase to RMB50.8 billion in 2030, with a CAGR of 7.0% from 2021 to 2030.

For more details, see "Business — Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)".

Our Core Product: LY-CovMab

We are developing LY-CovMab, which is a fully human monoclonal antibody manufactured by recombinant technology and used to counteract COVID-19. LY-CovMab could be a SARS-CoV-2 neutralizing antibody candidate for both of prevention and treatment of COVID-19. We began developing LY-CovMab in February 2020 and are conducting Phase 2 clinical trial in China. We expect to complete LY-CovMab's Phase 2 clinical trial at the earliest in 2023. However, given that the therapeutic area of LY-CovMab is infectious disease, the progress of its clinical trials is subject to various factors, such as the infectivity and severity of the virus, the virus variants which are spreading, and the patient enrollment process. We plan to launch LY-CovMab initially in China after we receive regulatory approval and may also explore the possibility of expanding the commercialization of LY-CovMab to other overseas markets. According to *in vitro* virus neutralization activity data, LY-CovMab has a neutralizing effect on Alpha, Delta, Gamma, Lambda variants, and has a limited neutralization effect on Omicron variant.

As the pathogen of COVID-19, SARS-CoV-2 is continuing to spread and cause the global pandemic with millions of confirmed COVID-19 cases including over 6.0 million deaths as of the Latest Practicable Date according to the data of the WHO. Patients are still facing few options for effective medications. According to the Frost & Sullivan Report, the disease is more likely to occur in older people. The Centers for Disease Control and Prevention ("**CDC**") reported that although individuals older than age 65 comprise 17% of the total population in the United States, they make up 31% of COVID-19 infections, 45% of hospitalizations, 53% of intensive care unit admissions, and 80% of deaths caused by this infection.

For more details, see "Business — Our innovative antibody portfolio — Our Core Product: LY-CovMab".

Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®)

We developed Boyounuo® (BA1101) as an Avastin® (bevacizumab) biosimilar, which is our first commercialized antibody drug product. Bevacizumab is a monoclonal antibody drug approved by the NMPA mainly for the treatment of mCRC, advanced metastatic or recurrent NSCLC, recurrent glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer. Based on data collected and analyzed from our Phase 3 clinical trial completed in June 2020, we concluded that the trial achieved bioequivalence in both primary and secondary endpoints. We received regulatory approval for Boyounuo® (BA1101) from the NMPA for the indication of mCRC and advanced metastatic or recurrent NSCLC in April 2021 and we commenced commercial sales of Boyounuo® (BA1101) in May 2021.

Subsequent to the successful launch of Boyounuo® (BA1101) in May 2021, we further made several achievements including (i) obtaining the NMPA approvals to extrapolate its indications to recurrent glioblastoma in July 2021 and epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in February 2022, which further broaden the product's market potential, and (ii) publishing two papers in *Cancer Communications and Expert Opinion on Biological Therapy* in May and December 2021, respectively, covering the clinical trial comparing its efficacy and safety with that of Avastin® in first-line treatment of Chinese patients with advanced metastatic or recurrent NSCLC, as well as the study comparing its PK profiles, safety and immunogenicity with those of Avastin® in healthy Chinese males.

For more details, see "Business — Our biosimilar portfolio — Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®)".

OUR OTHER DRUG CANDIDATES

BA9101 aflibercept intraocular injection (a biosimilar to Eylea®)

We are developing BA9101 as an Eylea® (aflibercept) biosimilar. Eylea® (aflibercept as its generic name) is primarily used to treat patients with wet age-related macular degeneration ("**wAMD**"), diabetic macular edema ("**DME**"), retinal vein occlusion ("**RVO**") and diabetic retinopathy ("**DR**"). It is a fusion protein composed of the extracellular binding domain of vascular endothelial growth factor ("**VEGF**") receptor fused with human IgG1 Fc domain. We began developing BA9101 in January 2015. The Phase 3 clinical trial in the treatment of wAMD is ongoing in China.

BA1104 (a biosimilar to Opdivo®)

We are developing BA1104 as an Opdivo® (nivolumab) biosimilar. Opdivo® (nivolumab as its generic name) is primarily used to treat patients with melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. In February 2021, we submitted to the CDE the IND application for BA1104, becoming one of the first domestic companies to submit the IND application for nivolumab biosimilars. In April 2021, we obtained the IND approval from the CDE. We initiated the Phase 1 clinical trial in China in September 2022 and plan to initiate the Phase 3 clinical trial in China in 2024.

BA5101 (a biosimilar to Trulicity®)

We are developing BA5101 as a Trulicity® (dulaglutide) biosimilar. Trulicity® (dulaglutide as its generic name) is primarily used to treat patients with type 2 diabetes. We obtained the IND approval in September 2021. In July 2022, BA5101 has entered into Phase 3 clinical trial in China.

BA1105

We are developing BA1105, which is a recombinant anti-Claudin 18.2 fully human IgG1 monoclonal antibody that introduces amino acid site-directed mutations through the Fc region to enhance the ADCC effect. We began developing BA1105 in June 2019 and are conducting Phase 1 clinical trial in China. Based on our pre-clinical and preliminary clinical findings, BA1105 has the potential to become the best targeted drug for the similar treatment of metastatic pancreatic cancer, advanced gastric cancer and adenocarcinoma of the esophagogastric junction.

BA1201

We are developing BA1201, which is an anti-PD-L1/TGF-β bifunctional fusion protein intended for the treatment of SCLC, NSCLC, cervical cancer, urothelial carcinoma, and advanced gastrointestinal tumors. In August 2022, we initiated Phase 1 clinical trial in China. This drug candidate is also our first new bispecific antibody drug under development that has been approved to initiate clinical trial. Different from the monoclonal antibodies against a single target, bispecific antibodies can bind to two targets at the same time and regulate two signaling pathways related to the treatment of cancer, which has unique advantages in cancer immunotherapy.

BA1106

BA1106 is an innovative CD25 fully human monoclonal antibody independently developed by us. CD25 antibody is a broad-spectrum immuno-oncology drug, with potential indications for cervical cancer, renal cancer, ovarian cancer, melanoma, pancreatic cancer, hepatocellular carcinoma, gastric cancer and breast cancer. In November 2021, we published the related research results of BA1106 in *Scientific Reports*, a sub-issue of *Nature* magazine. In September 2022, we have received the IND approval for BA1106. This makes BA1106 the first investigational anti-CD25 antibody to start clinical trials in China for treating solid tumors. As of the Latest Practicable date, we were preparing for the Phase 1 clinical trial of BA1106 in China.

BA1202

BA1202 is a bispecific antibody targeting CEA and CD3 independently developed by us through the bispecific T-cell engager technology platform. It is mainly used to treat advanced mCRC, pancreatic duct adenocarcinoma and other CEA-positive tumors. We were conducting the pre-clinical process research of BA1202 as of the Latest Practicable Date.

BA1301

BA1301 is an anti-Claudin 18.2 antibody-drug conjugate ("**ADC**") independently developed by us. It is mainly used to treat gastric cancer, esophageal cancer and pancreatic cancer. We submitted the IND application in October 2022.

BA2101

BA2101 is an IL4R long-acting molecular antibody independently developed by us. It may block IL-4 and IL-13 signaling pathways at the same time, regulate type 2 immunity, reduce the content of eosinophils and IgE, and treat allergic diseases caused by Th2 type immunity. It is mainly used to treat atopic dermatitis, asthma, sinusitis, pruritus and urticaria. In October 2022, we received the IND approval for BA2101. As of the Latest Practicable date, we were preparing for the Phase 1 clinical trial of BA2101 in China.

BA-CovMab

BA-CovMab is a fully human monoclonal antibody manufactured by recombinant technology and used to counteract COVID-19. We have been conducting the Phase 1 clinical trial in China since October 2022.

For more details, see "Business — Our biosimilar portfolio" and "Business — Our innovative antibody portfolio".

COMPETITION AND COMPETITIVE LANDSCAPE

The regional and global biologics industries, and the pharmaceutical industry generally, are highly competitive, with a large number of well-known multinational companies, regionally-strong players and companies in the pre-product commercialization phase. Many of our prospective competitors may have significant resources and brand awareness, and may be deeply entrenched in certain market segments, whether by geographic region or by drug type.

The players in the biologics industries, including us, generally face various challenges. Firstly, our biosimilar products face challenges from lower entry barriers, higher downward price pressure in light of the intense market competition, and in particular competing products that are at a more advanced development stages. See "Risk Factors — Risks relating to the commercialization of our drug candidates — Certain of our biosimilar products may not be as advanced in development as some of the equivalent biosimilar candidates being developed by our competitors, which may result in our competitors capturing significant first-entrant advantages with respect to their products" for further details. Bedsides, when conducting late-phases of clinical development of products we may face slower-than-expected patient enrolment, quality issues and unexpected safety concerns that may hinder our commercialization plan. See "Risk Factors — Risks relating to the development, clinical trials and regulatory approval of our drug candidates — We may encounter various delays in the preclinical programs, clinical development and regulatory approval process, which may result in delays in, or suspension of, the commercialization of our drug candidates" for further details. Furthermore, there is uncertainty on the growth of the COVID-19 drug market given that the pandemic is being contained and the virus has become less virulent, which may adversely impact our LY-CovMab and BA-CovMab. See "Risk Factors — Risks relating to the commercialization of our drug candidates — We may not be able to successfully commercialize LY-CovMab, one of our Core Products, or BA-CovMab, which may negatively affect our business, results of operations and business prospects" for further details.

With respect to our biosimilar candidates, we expect to compete based on our well-established and proven commercialization capability backed by marketing strategies implemented by dedicated marketing teams and our ability to produce drugs that are of similar quality and efficacy as the relevant reference drugs at lower costs. With respect to original or innovative drug candidates, we expect to compete primarily based on our ability to identify and address new or underserved treatment needs, whether due to a lack of existing drugs generally or as a result of such drugs being unavailable or unaffordable in certain regional markets (in which case making such drug candidates available at affordable prices would also be a key competitive factor). We expect to face significant competition from domestic and international pharmaceutical companies. Our major competitors are other biotech companies in China and elsewhere that focus on producing biologics whose reference drugs may be unavailable, unaffordable or non-existent.

Competition and competitive landscape of BA1102

According to the Frost & Sullivan Report, the global Xgeva® (denosumab) market size increased from US$1,708.8 million in 2017 to US$2,203.8 million in 2021, with a CAGR of 6.6%, and is expected to decrease to US$1,824.6 million in 2030. As of the Latest Practicable Date, there was no biosimilar to Xgeva® (denosumab) that has launched in any

market and there were two clinical-stage Xgeva® (denosumab) biosimilar candidates globally (outside of China), inclusive of BA1102 (by virtue of the clinical trial conducted for BA6101 in the EU). In China, there were two Xgeva® (denosumab) biosimilar candidates that had submitted the BLA and two Xgeva® (denosumab) biosimilar candidates that were in Phase 3 clinical trial stage as of the same date, inclusive of BA1102.

Competition and competitive landscape of BA6101

According to the Frost & Sullivan Report, the global Prolia® (denosumab) market size increased from US$2,164.2 million in 2017 to US$3,593.1 million in 2021, with a CAGR of 13.5%, and is expected to increase to US$3,984.7 million in 2030, with a CAGR of 1.2% from 2021 to 2030. There was no Prolia® (denosumab) biosimilars marketed in China from 2017 to 2020 according to the Frost & Sullivan Report. As of the Latest Practicable Date, there was no biosimilar to Prolia® (denosumab) that had launched in any market. As of the same date, globally (outside of China), there were 10 Prolia® (denosumab) biosimilar candidates which were in Phase 3 clinical stage and one Prolia (denosumab) biosimilar candidate which was in Phase 1 clinical stage, being BA6101. As of the Latest Practicable Date, in China, there were two Prolia® (denosumab) biosimilar candidates that had submitted the BLA, three Prolia® (denosumab) biosimilar candidates that were in Phase 3 clinical stage and two Prolia® (denosumab) biosimilar candidates that were in Phase 1 clinical stage. BA6101 was the only Prolia® (denosumab) biosimilar approved in China.

Competition and competitive landscape of LY-CovMab

According to the Frost & Sullivan Report, the global COVID-19 neutralizing antibody market exceeded US$9.5 billion in 2021. According to WHO, as of the Latest Practicable Date, the total global cumulative case number of COVID-19 was over 600 million. Taking into account the mass vaccination campaigns that were underway in many countries, the estimated market size for COVID-19 neutralizing antibody will likely decrease in the future. As of the Latest Practicable Date, there were one marketed and nine clinical-stage COVID-19 neutralizing antibodies in China, including LY-CovMab.

Competition and competitive landscape of Boyounuo® (BA1101)

According to the Frost & Sullivan Report, China bevacizumab market size increased from RMB1.7 billion in 2017 to RMB9.0 billion in 2021, with a CAGR of 51.4%, and is expected to increase to RMB18.4 billion in 2030, with a CAGR of 8.3% from 2021 to 2030. As of the Latest Practicable Date, there were nine NMPA approved bevacizumab in China, including the reference drug by Roche and eight domestic biosimilars, inclusive of Boyounuo® (BA1101).

For further details and the addressable market of our other drug candidates, see "Industry Overview."

OUR PLATFORMS

Our drug discovery platforms include Human Antibody Transgenic Mouse and Phage Display Technology, Bispecific T-cell Engager Technology and ADC Technology Platforms. We utilize our BA-huMab® and phage display technology platforms during antibody discovery. Our human antibody transgenic mice developed under the BA-huMab® platform contains 30 human antibody κ light chain variable region genes, 110

human antibody heavy chain variable region genes (IgM & IgG1). It can directly generate human antibodies without need for humanization, which significantly accelerates antibody discovery process and decreases immunogenicity risk. We have successfully identified potential candidates of over 10 targets through the human antibody transgenic mice BA-huMab®, with high affinity and high specificity. For example, LY-CovMab, BA1105, BA1106 and BA1201 were developed under the BA-huMab® platform. Our phage display technology platform offers a mature and advanced phage library construction technology. Quality of phage libraries is strictly controlled with the capacity of immunized libraries larger than 10^9 and sequence accuracy rate higher than 95%.

Our bispecific T-cell engager technology platform can exhibit high avidity with tumor target antigen by bivalent binding to achieve better drug efficacy, low affinity with T cells by monovalent binding to lower toxicity and significantly reduce the risk of cytokine release syndrome ("**CRS**"). For example, BA1202 was developed under the bispecific T-cell engager technology platform. We have established the ADC technology platform covering the whole process of ADC discovery and development. For example, BA1301 was developed under the ADC technology platform.

For further details, see "Business — Research and development — Discovery — Technology platforms".

INTELLECTUAL PROPERTY

As a biopharmaceutical company, we are keenly aware of the importance of establishing and protecting our intellectual property rights. We have filed a number of patent applications for our drug candidates in various jurisdictions, and expect to rely on a combination of patents, trademarks, trade secrets and other intellectual property rights, as well as employee and third-party confidentiality agreements, in order to safeguard our intellectual properties. As of the Latest Practicable Date, we had 25 granted patents and 44 pending patent applications worldwide. With respect to our Core Products, we had one issued patent and four pending patent applications in China and overseas jurisdictions as of the Latest Practicable Date. We are of the view that there is no material legal impediment for us to obtain the approvals for all of our pending patent applications, subject to the examination opinions from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications. Specifically, our legal advisors have checked and reviewed the legal status of our pending patent applications in relation to the Core Products in the public online databases of the China National Intellectual Property Administration (CNIPA), World Intellectual Property Organization (WIPO) and some other public patent databases as well as the information provided by us regarding the patent applications. Our legal advisors are not aware of any fact or legal impediment with respect to those pending patent applications that would preclude the issuance of patents with respect to such applications except that these patent applications remain subject to the examination opinions from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications. We are of the view, after having consulted our legal advisors, that we have been granted patents or applied for patent applications that cover material patentable features relating to our Core Products and Commercialized Product in each planned jurisdictions where relevant patents and/or patent applications have been obtained/filed.

Based on the FTO analysis of our Core Products, we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize our Core Products in China at the contemplated timeframe. Based on the FTO analysis of BA1102 and BA6101, we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize BA1102 and BA6101 in the United States and the EU at the contemplated timeframe. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to determine whether any existing patents cover a company's products, and whether making, using, offering to sell, or selling the products would infringe any existing patents.

As of the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceedings or claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent. Based on the review of public information, our PRC Legal Adviser did not find that we infringed on or misappropriated third parties' intellectual property rights during the Track Record Period and up to the Latest Practicable Date. Our Directors confirmed that we did not infringe on or misappropriate third parties' intellectual property rights, and we were not aware of any legal, arbitral or administrative proceedings of potential or confirmed infringement or misappropriation of any third parties' intellectual property rights by us, during the Track Record Period and up to the Latest Practicable Date.

For further details, see "Business — Intellectual property".

RESEARCH AND DEVELOPMENT

We boast our integrated biopharmaceutical platform, through which we have excelled in the discovery, development, manufacture and commercialization of antibody drugs with a focus on therapeutic areas of oncology, metabolism, autoimmunity and ophthalmology. We have accumulated substantial experience and know-how across all stages of antibody research and development, which enables us to efficiently develop antibody products from candidate generation to late-phase GMP manufacturing. As of June 30, 2022, our R&D team consisted of 250 employees in China and three employees in Boston in the United States covering biopharmaceutical discovery research, biotechnology research, biopharmaceutical analysis research, biological activity research, non-clinical research, pilot process research, clinical research, regulatory affairs, project management and intellectual property and other R&D functions, most of whom had R&D and clinical experience of more than six years.

We have a fully-fledged proprietary R&D technology platform focusing on antibody discovery and drug development. We have R&D teams and facilities located in Yantai and Nanjing in China, with rich experience and strong performance track record in drug discovery and development. We also have R&D team in Boston in the United States. We are one of the few biopharmaceutical companies in China capable of executing R&D throughout the whole product development process, from early candidate generation to eventual BLA filing and commercialization. We have independently developed all of our core drug candidates in-house, with proprietary know-how across the entire process. For the years ended December 31, 2020 and 2021 and for the six months ended June 30, 2021 and 2022, the research and development costs for the Core Products were RMB97.3

million, RMB50.8 million, RMB26.4 million and RMB21.3 million, respectively, representing 41.2%, 21.9%, 23.6% and 12.6% of our total research and development costs for the same period, respectively. The decrease of our research and development costs of our Core Products during the Track Record Period was mainly because of the capitalization of the expenditures incurred for our Core Products after they became eligible for capitalization.

While we carry out much of our research and development work in-house, we also engage Independent Third Party CROs who provide us with a range of technology and services necessary for complex pre-clinical studies and clinical trials. We have long-term relationships with a number of reputable CROs. We select CROs based on a number of factors, including their quality, reputation and research experience. We monitor the CROs to ensure they perform their duties to a standard in line with our protocols and industry benchmark to safeguard the integrity of the data collected from the trials and studies.

While in recent years we have primarily manufactured product candidates in-house in China for our clinical trials, in case of facing a shortage of our pilot production capacity, we have engaged CDMOs to produce small quantities of product candidates for our clinical trials in China. Going forward, we may still consider outsourcing excess pilot production needs to CDMOs from time to time, if necessary. We select our CDMOs by reviewing a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and the financial terms offered by them.

For further details, see "Business — Research and development".

MANUFACTURING

As of the Latest Practicable Date, we had a pilot and commercial production site for antibody products in Hi-tech Industrial Development Zone in Yantai (煙台高新區), Shandong province, which had a total GFA of approximately 33,504.1 sq.m. We own the underlying land use rights and buildings for the Yantai Site and all of the plant and equipment within the site. The Yantai Site houses a number of production lines which are used for (i) drug substance manufacturing process, with a capacity of total 1,700L for pilot production (comprising three 500L and one 200L single-use bioreactors) and 8,000L for commercial production (comprising two production lines each with two 2,000L single-use bioreactors), and (ii) drug product manufacturing process for both pilot and commercial production, consisting of (a) the vial filling formulation line with a designed production capacity of 2.5 million vials per annum, and (b) the pre-filled product formulation line of 3.5 million pre-filled syringes per annum. In 2021, we produced 303,294 vials and 36,296 pre-filled syringes for both our clinical trials and commercialization, representing a utilization rate of 12.0% and 1.0% of the vial filling formulation line and the pre-filled product formulation line, respectively, which is calculated by dividing the actual production volume by the designed production capacity per annum.

For further details, see "Business — Manufacturing".

COMMERCIALIZATION, SALES, MARKETING AND DISTRIBUTION

Leveraging our well-established and demonstrated commercialization capability backed by marketing strategies implemented by our dedicated sales and marketing team, we believe we are well positioned to achieve speed-to-market and rapid ramp-up of product sales. Internally, we have a dedicated in-house sales and marketing team with extensive industry experience and they develop and implement marketing and sales initiatives and plans of our product and drug candidates in their scheduled rollouts. Externally, we collaborate with various resourceful business partners which lay the foundation for our strong commercialization capability. Our collaboration with experienced third party promoters effectively publicizes and maximize market potential of our products.

To supplement our in-house sales and marketing capabilities, we engage experienced third-party promoters to publicize and maximize market potential of our products. We select third-party promoter based on their qualifications, reputation, marketing experience, management capabilities and hospital coverage. Specifically, on May 26, 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, regarding the promotion rights to Boyounuo® (BA1101), under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, under which we granted OcuMension certain exclusive right to promote and commercialize BA9101 in China, and we are responsible for conducting certain initial stages of the Phase 3 clinical trial and commercial production as well as submitting the BLA of BA9101 and OcuMension is responsible for completing the rest of Phase 3 clinical trial.

We sell our launched product, Boyounuo® (BA1101) to third-party distributors, and we derive all of our revenue from our sales to distributors. Our distributors are our direct customers, and are responsible for on-selling and delivering our products to hospitals. As of June 30, 2022, we had an extensive distribution network of 160 distributors, penetrating selected regions and reaching more than 1,100 target hospitals and institutions in China. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China.

We believe an optimal pricing strategy is the key to develop and maintain our long-term competitiveness. On the one hand, biopharmaceutical companies, like us, need to compete in various aspects, including pricing, in order to gain market share due to the strong competition in the industry. On the other hand, in order to achieve a sustainable development, biopharmaceutical companies including us also need to maintain a reasonable profit level so they can recoup their investment costs. As advised by Frost & Sullivan, in general the price of biosimilar can commensurate with its investment cost. Striking a balance between maintaining competitive price and a reasonable profit level via an optimal pricing strategy becomes an important task for biopharmaceutical companies. Furthermore, centralized procurement in China has strong bargaining power over pricing of biopharmaceutical products. See "Risk Factors — Risks relating to the commercialization of our drug candidates — Even if we are able to commercialize any drug candidates, the drugs may become subject to national or other third-party reimbursement practices, healthcare reform initiatives or unfavorable pricing regulations, which could harm our business" for further details.

For further details, see "Business — Commercialization, sales, marketing and distribution".

CUSTOMERS

In 2021 and for the six months ended June 30, 2022, we derived all of our revenue from the sales of Boyounuo® (BA1101). We did not record any revenue in 2020. For 2021, all of our five largest customers were distributors and the aggregate sales to our five largest customers were RMB129.9 million, representing 81.8% of our revenue. Sales to our largest customer for the same period were RMB48.3 million, representing 30.4% of our revenue. For the six months ended June 30, 2022, all of our five largest customers were distributors and the aggregate sales to our five largest customers were RMB172.8 million, representing 78.3% of our revenue. Sales to our largest customer for the same period were RMB90.0 million, representing 40.8% of our revenue.

For further details, see "Business — Customers".

RAW MATERIALS AND SUPPLIERS

Our main raw materials used in the production process for drug candidates and drugs include glucose, polysorbate, reagents, cell culture media, chromatography resins, excipients, packaging materials and consumables, such as single-use bioreactors and buffer preparation bags. We purchased these raw materials and supplies from a variety of suppliers in China and globally, including the United States, Germany, Switzerland, the United Kingdom and Japan. We had also engaged service providers such as CROs and CDMOs primarily to support our clinical trials and to produce our drug candidates.

For the years ended December 31, 2020 and 2021, purchases from our five largest suppliers in aggregate accounted for 28.9% and 19.7% of our total purchases, respectively, and purchases from our largest supplier accounted for 7.4% and 5.4% of our total purchases for the same periods, respectively. For the six months ended June 30, 2022, purchases from our five largest suppliers in aggregate accounted for 21.9% of our total purchases, and purchases from our largest supplier accounted for 6.2% of our total purchases for the same period, respectively.

For further details, see "Business — Raw materials and suppliers".

OUR STRENGTHS

We believe our competitive strengths include:

- Robust and risk-balanced portfolio that brings us clear short-term commercial visibility and fuels long-term sustainable growth;
- Integrated biopharmaceutical platform with proprietary R&D technology and validated outstanding drug development capability;
- Strong CMC capability supporting drug development and enabling enhanced cost efficiencies in commercial scale production;
- Well-established commercialization capability enabling speed-to-market with a proven track record; and
- Management team with extensive industry experience and market insight, supported by reputable investors.

OUR STRATEGIES

Our vision is to become a leading biopharmaceutical company. We plan to expand our overseas footprint leveraging our aforementioned strengths and the leading position we are thriving to maintain in China. In order to achieve our vision and goals, we plan to pursue the following strategies. To achieve this vision, we plan to implement the following strategies:

- Accelerate clinical development of our pipeline products towards commercialization in selected overseas markets;
- Enrich our innovative antibody portfolio to maximize our long-term commercial potential;
- Further strengthen our marketing capability and accelerate the commercialization of our drug candidates leveraging our experience in commercializing Boyounuo® (BA1101);
- Continue to expand in-house manufacturing capability; and
- Explore collaboration with reputable international partners to expand overseas presence.

PRE-[REDACTED] INVESTMENTS AND CONTROLLING SHAREHOLDERS

We have completed two rounds of financing from our Pre-[**REDACTED**] Investors and raised an aggregate amount of approximately RMB1.09 billion of proceeds for our development. Our broad and diverse base of Pre-[**REDACTED**] Investors consists of private equity and venture capital funds and investment holding companies, some with specific focus on the life sciences or biomedicine. Among the Pre-[**REDACTED**] Investors, Sophisticated Investors in our Company include Advantech Capital, CCB Juyuan, SD Jiazhi LP, SZ BioResearch, Qianhai Equity Fund, Starr International, Zhongyuan Qianhai and Yantai Innovative, which will hold, in aggregate, approximately [**REDACTED**]% of our Company's total share capital upon completion of the [**REDACTED**] (without taking into account any Shares which may be issued pursuant to the exercise of the [**REDACTED**]). See "Pre-[**REDACTED**] Investments" for the identities of our Pre-[**REDACTED**] Investors and the key terms of their investments.

Our Controlling Shareholders are Luye Pharma, AsiaPharm, Luye HK, Yantai Luye and Shandong Luye, which will be interested in an aggregate of approximately [**REDACTED**]% of our Company's total share capital immediately following the [**REDACTED**] (without taking into account any Shares which may be issued pursuant to the exercise of the [**REDACTED**]). As of the Latest Practicable Date, Shandong Luye was wholly owned by Yantai Luye, which in turn is indirectly wholly owned by Luye Pharma through AsiaPharm and Luye HK. Accordingly, Luye Pharma, AsiaPharm, Luye HK, Yantai Luye and Shandong Luye constitute a group of our Controlling Shareholders under the Listing Rules. Luye Pharma is a company listed on the Main Board of the Stock Exchange (stock code: 2186), which principally engages in the research, development, manufacturing, marketing, and sale of chemical drugs through its subsidiaries, including AsiaPharm, Luye HK, Yantai Luye and Shandong Luye.

SUMMARY KEY FINANCIAL INFORMATION

This summary historical financial information set forth below have been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants' Report set out in Appendix I to this document, as well as the information set forth in "Financial Information" of this document. Our financial information was prepared in accordance with IFRS.

Summary consolidated statement of profit or loss

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2020	2021	2021	2022
			(unaudited)	
	(RMB in thousands)			
REVENUE	–	158,704	12,094	220,690
Cost of sales	–	(52,190)	(3,311)	(73,421)
Gross profit	–	106,514	8,783	147,269
Other income and gains	12,073	13,365	5,745	13,508
Research and development costs	(236,317)	(231,567)	(111,558)	(169,057)
Administrative expenses	(4,464)	(42,165)	(18,220)	(37,563)
Selling and distribution expenses	–	(54,048)	(5,874)	(100,827)
Other expenses	(11)	(5,917)	(1,228)	(3)
Finance costs	(11,819)	(11,599)	(5,575)	(6,622)
LOSS BEFORE TAX	(240,538)	(225,417)	(127,927)	(153,295)
Income tax expense	–	–	–	–
LOSS FOR THE YEAR/PERIOD	(240,538)	(225,417)	(127,927)	(153,295)

During the Track Record Period, we derived revenue solely from the sales of Boyounuo® (BA1101) in China to our distributors since its launch in May 2021. Our revenue was nil and RMB158.7 million for the years ended December 31, 2020 and 2021, respectively, and RMB12.1 million and RMB220.7 million for the six months ended June 30, 2021 and 2022, respectively.

Our administrative expenses increased significantly from RMB4.5 million for the year ended December 31, 2020 to RMB42.2 million for the year ended December 31, 2021, primarily due to the increases in (i) staff costs and expenses related to the ESOP for our administrative personnel from RMB2.0 million for the year ended December 31, 2020 to RMB28.9 million for the year ended December 31, 2021, (ii) others from RMB0.6 million for the year ended December 31, 2020 to RMB5.4 million for the year ended December 31, 2021 mainly reflecting the increases in property tax, stamp duty and recruiting costs, which

were in line with our expanded business and (iii) [**REDACTED**] expenses of RMB[**REDACTED**] incurred in 2021 for the proposed [**REDACTED**]. Our administrative expenses increased significantly from RMB18.2 million for the six months ended June 30, 2021 to RMB37.6 million for the six months ended June 30, 2022, primarily due to the increase in the [**REDACTED**] expenses from RMB[**REDACTED**] for the six months ended June 30, 2021 to RMB[**REDACTED**] for the six months ended June 30, 2022 as the proposed [**REDACTED**] progressed. Our selling and distribution expenses increased significantly from RMB5.9 million for the six months ended June 30, 2021 to RMB100.8 million for the six months ended June 30, 2022, mainly attributable to the increase in the promotion expenses from RMB3.8 million for the six months ended June 30, 2021 to RMB93.9 million for the six months ended June 30, 2022 mainly incurred for independent third-party promotors attributable to the sales of Boyounuo® (BA1101), which was generally in line with the revenue growth during the same period.

For the years ended December 31, 2020 and 2021, we had a total loss for an amount of RMB240.5 million and RMB225.4 million, respectively, and for the six months ended June 30, 2021 and 2022, it amounted to RMB127.9 million and RMB153.3 million, respectively. Our total loss for the year/period mainly resulted from research and development costs and administrative expenses, as well as selling and distribution expenses which exceeded our revenue. See "Financial Information — Description of major line items in our consolidated statement of profit or loss" for further details.

Summary consolidated statements of financial position

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated, which has been extracted from the Accountants' Report set out in Appendix I to this document:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Total current assets	92,062	939,850	762,448
Total non-current assets	815,968	1,166,754	1,262,928
Total assets	**908,030**	**2,106,604**	**2,025,376**
Total current liabilities	396,177	260,482	313,341
Total non-current liabilities	30,264	294,435	303,485
Total liabilities	**426,441**	**554,917**	**616,826**
Net current (liabilities)/assets	**(304,115)**	**679,368**	**449,107**
Net assets	**481,589**	**1,551,687**	**1,408,550**

We had net current liabilities of RMB304.1 million as of December 31, 2020, primarily attributable to (i) due to related parties of RMB284.8 million mainly representing the loans from Shandong Luye and (ii) trade and notes payables of RMB91.6 million mainly in connection with our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process, partially offset by prepayments, other receivables and other assets of RMB68.1 million primarily attributable to prepayments in connection with our purchase of raw materials used and related expenses for research and development activities, and raw materials used for pilot and commercial production as well as value added tax (the "**VAT**") recoverable. We had net current assets of RMB679.4 million as of December 31, 2021, primarily due to cash and cash equivalents of RMB531.7 million mainly attributable to the proceeds we received through pre-[**REDACTED**] investments and trade and notes receivables of RMB107.3 million mainly related to our sales of Boyounuo® (BA1101), partially offset by (i) trade and notes payables of RMB138.7 million mainly reflecting our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process and (ii) other payables and accruals of RMB79.0 million mainly reflecting (a) accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) and (b) payroll payables. We had net current assets of RMB449.1 million as of June 30, 2022, primarily due to (i) cash and cash equivalents of RMB312.2 million mainly attributable to the proceeds we received through pre-[**REDACTED**] investments and from the sales of Boyounuo® (BA1101), (ii) inventories of RMB140.9 million consisting of raw materials used in manufacturing processes for our drug products as well as work in progress and finished goods and (iii) trade and notes receivables of RMB139.0 million mainly related to our sales of Boyounuo® (BA1101), partially offset by (i) other payables and accruals of RMB151.3 million mainly reflecting (a) accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) and (b) payroll payables and (ii) trade and notes payables of RMB120.5 million mainly reflecting our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process. For the analysis on our net current assets as of October 31, 2022, see "Financial Information — Description of major line items in our consolidated statements of financial position".

We had intangible assets of RMB325.3 million, RMB566.0 million and RMB653.2 million, respectively, as of December 31, 2020 and 2021 and June 30, 2022, representing 35.8%, 26.9% and 32.3%, respectively, of our total assets as of each such date. Our intangible assets primarily consist of (i) technology know-how mainly representing proprietary technology, (ii) software and (iii) deferred development costs mainly representing the expenditure incurred for our drug candidates which were eligible for capitalization. See "Risk Factors — Risks relating to our financial prospects and need for additional capital — We have a large balance of intangible assets and we may incur significant impairment charges which could materially impact our financial position" for further details.

Our net assets increased from RMB481.6 million as of December 31, 2020 to RMB1,551.7 million as of December 31, 2021, reflecting changes in equity mainly comprising capital contribution from shareholders of RMB1,230.2 million and loss for the year in 2021 of RMB225.4 million, and slightly decreased to RMB1,408.6 million as of June 30, 2022, reflecting changes in equity mainly due to the loss for the period of RMB153.3 million.

See "Financial Information — Description of major line items in our consolidated statements of financial position" for further details.

Summary consolidated statements of cash flows

The following table sets forth our cash flows for the periods indicated:

	Years ended December 31,		Six months ended June 30,	
	2020	**2021**	**2021**	**2022**
			(unaudited)	
	(RMB in thousands)			
Net cash flows used in operating activities	(506,720)	(246,278)	(151,691)	(114,212)
Net cash flows used in investing activities	(18,787)	(432,296)	(260,223)	(97,604)
Net cash flows from/(used in) financing activities	527,233	1,211,729	1,016,220	(11,462)
Net increase/(decrease) in cash and cash equivalents	1,726	533,155	604,306	(223,278)
Cash and cash equivalents at the beginning of the year/period	1,903	3,629	3,629	531,703
Effect of foreign exchange rate changes, net	–	(5,081)	(462)	3,816
Cash and cash equivalents at the end of the year/period	**3,629**	**531,703**	**607,473**	**312,241**

During the Track Record Period, we have incurred negative cash flows from our operations. Net cash used in operating activities primarily comprises our loss before tax for the period adjusted by (i) non-operating items and non-cash items; and (ii) changes in working capital.

For the six months ended June 30, 2022, we had net cash used in operating activities of RMB114.2 million primarily as a result of loss before tax of RMB153.3 million.

For the year ended December 31, 2021, we had net cash used in operating activities of RMB246.3 million primarily as a result of loss before tax of RMB225.4 million.

For the year ended December 31, 2020, we had net cash used in operating activities of RMB506.7 million primarily as a result of loss before tax of RMB240.5 million.

Our cash burn rate refers to the average monthly (i) net cash used in operating related activities, including research and development costs, purchase amount of property, plant and equipment as well as additions to intangible assets and (ii) net cash used in serving our indebtedness including payment of lease liabilities, loan principal and interest. Assuming an average cash burn rate going forward of 1.0 times of the level in 2021 of net cash used in operating related activities and taking into account the scheduled

payment of our indebtedness, we estimate that our cash and cash equivalents as of October 31, 2022 will be able to maintain our financial viability for five months, or, if we also take into account the estimated [**REDACTED**] (based on the low-end of the indicative [**REDACTED**]) from the [**REDACTED**], eight months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

Key financial ratios

The table below sets forth, as of the dates indicated, certain of our key financial ratios:

	For the year ended/As of December 31,		For the six months ended/As of June 30,
	2020	**2021**	**2022**
Gross margin[(1)]	N/A[(2)]	67.1%	66.7%
Current ratio[(3)]	23.2%	360.8%	243.3%
Quick ratio[(4)]	18.3%	322.9%	198.4%

Notes:

(1) Gross margin is calculated as gross profit divided by revenue, multiplied by 100%.

(2) We did not have gross margin in 2020, as we only started to generate revenue in 2021.

(3) Current ratio is calculated as current assets divided by current liabilities, multiplied by 100%.

(4) Quick ratio is calculated as current assets minus inventories then divided by current liabilities, multiplied by 100%.

[REDACTED] STATISTICS

	Based on the [REDACTED] of HK[REDACTED] per H Share	Based on the [REDACTED] of HK$[REDACTED] per H Share
Market capitalization of our H Shares (approximately)[(1)]	HK$[**REDACTED**]	HK$[**REDACTED**]
Unaudited pro forma adjusted consolidated net tangible asset value per Share[(2)]	HK$[**REDACTED**]	HK$[**REDACTED**]

Notes:

(1) The calculation is based on the assumption that [**REDACTED**] H Shares in issue immediately following the completion of the [**REDACTED**], assuming that the [**REDACTED**] is not exercised.

(2) The unaudited pro forma adjusted net tangible asset value per Share is calculated after the adjustment referred to in "Unaudited Pro Forma Financial Information" in Appendix II to this document and on the basis of [**REDACTED**] H Shares in issue immediately following the completion of the [**REDACTED**], assuming that the [**REDACTED**] is not exercised.

FUTURE PLANS AND [REDACTED]

See "Business — Our strategies" for a detailed description of our future plans and strategies.

We estimate that we will receive [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**], after deducting [**REDACTED**], fees and estimated expenses payable by us in connection with the [**REDACTED**], and assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] range stated in this document, and without taking into account the [**REDACTED**].

We intend to use the [**REDACTED**] we will receive from the [**REDACTED**] for the following purposes and in the amounts set out below, subject to changes in light of our evolving business needs and changing market condition:

- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for the research and development of our Core Products.
  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1102.
  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA6101.
  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for LY-CovMab.
- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for the research and development of other products in our pipeline.
  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for our biosimilar candidates of BA9101, BA1104 and BA5101.
  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for our innovative antibody candidates of BA1105, BA1201, BA-CovMab, BA1106, BA1202, BA1301 and BA2101.
- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for commercialization purposes.
- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for working capital and other general corporate purposes.

For further details, see "Future Plans and [**REDACTED**]".

DIVIDENDS

We did not declare or pay any dividends during the Track Record Period and we do not have a fixed dividend payout ratio. The Board has absolute discretion as to whether to declare any dividend for any year and, if it decides to declare a dividend, how much to

declare. The Board will submit such proposal in respect of dividend payments to the Shareholders' general meeting for approval. The amount of any dividends to be declared or paid will depend on, among other things, applicable laws and regulations, our results of operations, cash flows, financial condition and operating and capital requirements. Any future declaration of dividends may or may not reflect our prior declarations of dividends.

[REDACTED] EXPENSES

[**REDACTED**] expenses represent professional fees, [**REDACTED**] and other fees incurred in connection with the [**REDACTED**]. We expect to incur total [**REDACTED**] expenses of approximately HK$[**REDACTED**] (assuming the [**REDACTED**] is not exercised and based on the [**REDACTED**] of HK$[**REDACTED**] per [**REDACTED**], being the mid-point of the [**REDACTED**] range), of which approximately RMB[**REDACTED**] and RMB[**REDACTED**] , respectively, has been charged to profit or loss in 2021 and for the six months ended June 30, 2022. The total [**REDACTED**] expenses consist of approximately HK$[**REDACTED**] [**REDACTED**] fees (including [**REDACTED**] and incentive fee, SFC transaction levy, Stock Exchange trading fee and AFRC transaction levy) and approximately HK$[**REDACTED**] non-[**REDACTED**] fees mainly including (i) fees and expenses of professional parties such as legal advisor(s), accountant(s) and other professional parties of approximately HK$[**REDACTED**] and (ii) other fees and expenses of approximately HK$[**REDACTED**]. Among the total [**REDACTED**] expenses, approximately HK$[**REDACTED**] is expected to be charged to profit or loss, and approximately HK$[**REDACTED**] directly attributable to the issue of the Shares is expected to be deducted from equity upon the completion of the [**REDACTED**]. Our total [**REDACTED**] expenses are estimated to account for [**REDACTED**]% of the [**REDACTED**] of the [**REDACTED**]. The [**REDACTED**] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS OF OUR BUSINESS SUBSEQUENT TO THE TRACK RECORD PERIOD

Milestones achieved on Commercialized Product and other product candidates

We have continued to expand our market of Boyounuo® (BA1101) in China and as of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China.

In July 2022, BA5101 has entered into Phase 3 clinical trial in China. The Phase 1 clinical studies have shown that BA5101 has biological similarity with Trulicity®. The Phase 3 clinical trial of BA5101 is a multi-center, randomized, open, parallel and positive-controlled clinical study in Chinese adult patients with type 2 diabetes to compare the efficacy, safety, immunogenicity and PK characteristics of BA5101 and Trulicity®.

In September 2022, we have received the IND approval for BA1106. This makes BA1106 the first investigational anti-CD25 antibody to start clinical trials in China for treating solid tumors. As of the Latest Practicable date, we were preparing for the Phase 1 clinical trial of BA1106 in China, and we plan to initiate the Phase 1 clinical trial in China in the first quarter of 2023.

Recently, we made major progress with an innovative drug candidate (BA-CovMab), a new generation broadly neutralizing antibody for treating COVID-19 developed by us under our BA-huMab® and phage display technology platforms. In September 2022, BA-CovMab was approved for clinical trials by the CDE. We initiated the Phase 1 clinical trial of BA-CovMab in China in October 2022. See "Business — Our innovative antibody portfolio — BA-CovMab" for more details.

In November 2022, we received the regulatory approval to commence commercialization of BA6101 in China. As of the Latest Practicable Date, we were in the process of preparing the launch of Boyoubei® (博优倍®), which is the brand name of BA6101.

We may record a significant increase in loss for the year ending December 31, 2022 primarily because we expect to incur more R&D expense to advance the development of our drug candidates.

Impact of the COVID-19 Outbreak

The outbreak of COVID-19 has caused illness in, and killed, many people in and outside China, caused a temporary suspension of production and shortage of labor and raw materials in affected regions, and disrupted local and international travel and the economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in the PRC and other affected countries.

Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 in several parts of China due to the spread of the Omicron variant, including some of our regional markets such as Shanghai, Guangdong Province, Shandong Province and Jilin Province, and various restrictive measures, such as lockdowns, quarantines, closure of work places, travel restrictions and home office policies have been implemented. As a result of the restrictive measures, our sales of Boyounuo® (BA1101) to some extent have been affected by patients' limited access to medical services in the affected regions, and we also experienced four to six months delays in the patient enrollment process of some clinical trials in China.

However, the restrictive measures have not had any material impact on our regulatory and clinical trial plans of the Core Products and pipeline candidates, our production capability, our commercialization plans or our overall financial performance. We also believe our sales of Boyounuo® (BA1101) will resume its normal level after the lifting of various restrictive measures primarily because of its continuing strong demand in China.

Our Directors confirmed that the COVID-19 outbreak did not have any material adverse impact on our business operations and financial performance as of the Latest Practicable Date, primarily because: (i) there had been no material disruption of our ongoing clinical trials of our Core Products; (ii) we had not encountered any material supply chain disruption; and (iii) there had been no material disruption of our sales and marketing activities. We cannot foresee when the COVID-19 outbreak will become completely under control or whether COVID-19 will have a material and adverse impact on our business going forward.

The extent to which the COVID-19 outbreak impacts our business, results of operations and financial condition will depend on many factors beyond our control, including the extent of resurgences of the disease and its variants, vaccine distribution and other actions in response to the virus or to contain its impact. It is uncertain when and whether COVID-19 could be contained globally. We are closely monitoring impact of COVID-19 outbreak on us and plan to continue implementing measures necessary to ease the impact of the outbreak on our operations. While we continue to assess the impact of the COVID-19 outbreak, we are unable to accurately predict the full impact of COVID-19. We cannot assure you that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial condition or prospects. Our operations may also be adversely affected if any of our employees or employees of our distributors, suppliers and other business partners are suspected of contracting or contracted COVID-19 or become subject to restricted measures. In addition, the commencement of new clinical trials for drug candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. For more details, see "Risk Factors — Risks relating to our operations — Our business and operations could be adversely affected by the effects of health pandemics or epidemics, including the outbreak of COVID-19, in regions where we, or third parties on which we rely, have significant manufacturing facilities, concentrations of clinical trial sites or other business operations".

Our Directors confirm that, having performed reasonable due diligence on our Group, there has been no material adverse change in our financial or trading position or prospects since June 30, 2022 and up to the date of this document.

KEY RISK FACTORS

We are a biopharmaceutical company seeking to **[REDACTED]** on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours, including the following:

- Certain of our biosimilar products may not be as advanced in development as some of the equivalent biosimilar candidates being developed by our competitors, which may result in our competitors capturing significant first-entrant advantages with respect to their products;

- We may not achieve favorable results for our drug candidates in clinical trials, and cannot give any assurance that any of our drug candidates currently in development will receive regulatory approval, which could hinder or halt their development;

- Clinical development involves a lengthy and expensive process with no assured outcome;

- Successful results in earlier studies in the clinical development process may not be predictive of future trial results;

- We may encounter various delays in the preclinical programs, clinical development and regulatory approval process, which may result in delays in, or suspension of, the commercialization of our drug candidates;

- We have a large balance of intangible assets and we may incur significant impairment charges which could materially impact our financial position.

- We incurred net losses during the Track Record Period and we may continue to incur losses in the near future and may not achieve or maintain profitability. Investors are at risk of losing substantially all of their investments in our H Shares;

- We had negative cash flow from operating activities throughout the Track Record Period and we will likely need substantial additional funding for our drug development programs and commercialization efforts, which may not be available on acceptable terms, or at all; and

- We have only recently begun commercializing our drug products and have just started to generate revenue from product sales, and we cannot assure you that we will be able to generate substantial revenue in the future.

See "Risk Factors" for further details.

THE [REDACTED]

The **[REDACTED]** of our Company constitutes a **[REDACTED]** of our Company from Luye Pharma. Luye Pharma considers that the **[REDACTED]** will be commercially beneficial to Luye Pharma, our Company and our Shareholders as a whole as the **[REDACTED]** will, among other things (i) enable our shareholders and investors to appraise the strategies, success factors, functional exposure, risks and returns of our Group and the Luye Group separately; (ii) enable our Group to build our identity as a separately **[REDACTED]** group, to have a separate fund-raising platform and to broaden our investor base; and (iii) enable more focused development, strategic planning and better allocation of resources for the Luye Group and our Group with respect to their respective businesses. **[REDACTED]** will be entitled to participate in the **[REDACTED]** on a **[REDACTED]** basis as to allocation only by way of the **[REDACTED]**. See "Structure of the **[REDACTED]**" for further details.

We mainly engage in developing, manufacturing and commercializing biologics, while the Luye Group mainly engages in the research, development, manufacturing, marketing, and sale of chemical drugs. Biologics and chemical drugs have different mechanisms of action, development and production technologies as well as treatment applications and usages. Two drugs of our Group (i.e BA1101 and LY01616) have overlapping indications with those of the Luye Group, but they differ from each other in their uses in treatments or target patient types. See "Relationship with our Controlling Shareholders — Delineation of Business — Largely different medical indications" for further details of such differences.

We also conduct our R&D independently of the Luye Group. All of our Core Products and Commercialized Product were developed by our own R&D departments and personnel, despite a limited number of staff members of the Luye Group who were involved in the provision of certain organization, coordination or other support services for clinical trials of some of these products. During the Track Record Period and up to the Latest Practicable Date, all of our key technology talents and R&D staff have entered into employment contracts with our Group. We have our own equipment and facilities required for R&D and the production lines dedicated to the development and production of antibody drugs. The R&D systems, capabilities, and technologies of our Company are completely independent from those of the Luye Group due to the different product types. See "Relationship with our Controlling Shareholders" for further details of our Controlling Shareholders and the business delineation between our businesses and the businesses of the Luye Group. Having considered the above and the factors elaborated in the section headed "Relationship with our Controlling Shareholders — Delineation of Business", our Directors believe and the Joint Sponsors concur that there is clear delineation between our business and the businesses of the Luye Group.

In this document, unless the context otherwise requires, the following terms shall have the meanings set out below. Certain other terms are explained in the section headed "Glossary of Technical Terms" in this document.

"Accountants' Report"	the accountants' report of our Company, the text of which is set out in Appendix I to this document
"Advantech Capital"	Advantech Capital Investment XIV Limited, a company incorporated with limited liability in the BVI December 27, 2018 and one of our Pre-**[REDACTED]** Investors
"AFRC"	the Accounting and Financial Reporting Council

[REDACTED]

"Articles of Association" or "Articles"	articles of association of our Company adopted on March 25, 2022 which shall become effective as of the date on which the H Shares are **[REDACTED]** on the Stock Exchange, as amended from time to time, a summary of which is set out in "Summary of Articles of Association" in Appendix V to this document
"Asian Alliance"	Asian Alliance (Hong Kong) Limited (亞聯藥業(香港)有限公司), a company incorporated with limited liability in Hong Kong on July 31, 2019 and one of our Pre-**[REDACTED]** Investors
"Asiapharm"	Asiapharm Investments Ltd., a company incorporated with limited liability in Bermuda on July 2, 2003 and one of our Controlling Shareholders
"associate(s)"	has the meaning ascribed to it under the Listing Rules

[REDACTED]

"AstraZeneca China"	AstraZeneca (Wuxi) Trading Co., Ltd.* (阿斯利康(無錫)貿易有限公司), one of our collaborators and an Independent Third Party
"Audit Committee"	the audit committee of the Board

[REDACTED]

"Boan Boston"	Boan Boston LLC, a limited liability company formed under Delaware law on October 20, 2020 and an indirect wholly-owned subsidiary of our Company
"Boan Nanjing"	Nanjing Boan Biotechnology Co., Ltd. (南京博安生物技術有限公司), a company established in the PRC on July 15, 2020 and a direct wholly-owned subsidiary of our Company
"Boan Singapore"	Boan Singapore Innovation Center Pte. Ltd., a company incorporated with limited liability in Singapore on October 20, 2020 and a direct wholly-owned subsidiary of our Company
"Board" or "Board of Directors"	the board of directors of our Company
"Brill Aimei"	Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)), a limited partnership established in the PRC on December 31, 2020 and one of our Pre-**[REDACTED]** Investors
"Brill Luoyi"	Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited Partnership) (寧波梅山保税港區博睿羅伊股權投資合伙企業(有限合伙)), a limited partnership established in the PRC on March 2, 2017 and one of our Pre-**[REDACTED]** Investors

"business day"	any day (other than a Saturday, Sunday or public holiday) on which banks in Hong Kong are generally open for business
"BVI"	British Virgin Islands
"CAGR"	compound annual growth rate, which is calculated by dividing the amount at the end of the period by the amount of the beginning of that period, raising the result to an exponent of one divided by the number of years in the period, and subtracting one from the subsequent result

[REDACTED]

[**REDACTED**]

"CCB Juyuan"	CCB Juyuan Investment Management (Beijing) Co., Ltd. (建銀聚源投資管理(北京)有限公司), a company established in the PRC on December 17, 2014 and one of our Pre-[**REDACTED**] Investors
"CDE"	Center for Drug Evaluation (藥品審評中心) of the NMPA
"close associate(s)"	has the meaning ascribed to it under the Listing Rules
"CNIPA"	China National Intellectual Property Administration (國家知識產權局)
"Commercialized Product"	Boyounuo® (BA1101)
"Companies Ordinance"	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Companies (Winding Up and Miscellaneous Provisions) Ordinance"	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Company" or "our Company"	Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司) (formerly known as 山东博安生物技术有限公司), a limited liability company established in the PRC on December 30, 2013 and converted into a joint stock company with limited liability on March 29, 2021
"connected person(s)"	has the meaning ascribed to it under the Listing Rules
"Controlling Shareholder(s)"	has the meaning ascribed to it under the Listing Rules, and unless the context otherwise requires, refers to Shandong Luye, Yantai Luye, Luye HK, AsiaPharm and Luye Pharma
"core connected person(s)"	has the meaning ascribed to it under the Listing Rules

"Core Product(s)"	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Products refer to BA1102, BA6101 and LY-CovMab
"COVID-19"	a viral respiratory disease caused by the severe acute respiratory syndrome coronavirus 2
"CSDC"	China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司)
"CSRC"	China Securities Regulatory Commission (中國證券監督管理委員會)
"Deed of Indemnity"	the deed of indemnity dated [●] and executed by our Controlling Shareholders in favor of our Company (for ourselves and as trustee for our subsidiaries), details of which are set out in "Statutory and General Information — D. Other information — 2. Tax and other indemnities" in Appendix VI to this document
"Director(s)"	the directors of our Company, including all executive, non-executive and independent non-executive directors
"Domestic Share(s)"	ordinary Shares in the share capital of our Company with a nominal value of RMB1.00 each, which are subscribed for and paid for in RMB
"EIT Law"	the PRC Enterprise Income Tax Law (中華人民共和國企業所得税法), as amended, supplemented or otherwise modified from time to time
"EMA"	the European Medicines Agency, a decentralized agency of the EU
"ESOP Entity(ies)"	Yantai Bofa, Yantai Bolian and Yantai Bosheng
"Extreme Conditions"	any extreme conditions or events, the occurrence of which will cause interruption to the ordinary course of business operations in Hong Kong and/or that may affect the [**REDACTED**] or the [**REDACTED**]
"FDA"	the United States Food and Drug Administration

"Frost & Sullivan"	Frost & Sullivan, our industry consultant and an Independent Third Party
"Frost & Sullivan Report"	the market research report provided by Frost & Sullivan, which was commissioned by our Group in relation to, among other things, the overview of the industries in which our Group operates or intends to operate
	[REDACTED]
"Group", "our Group", "we" or "us"	our Company and our subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of our present subsidiaries, the business operated by such subsidiaries or their predecessors (as the case may be)
"GTJA Huike"	Beijing GTJA Huike Venture Capital Partnership (Limited Partnership) (北京高特佳匯科創業投資合伙企業(有限合伙)), a limited partnership established in the PRC on May 16, 2019 and one of our Pre-**[REDACTED]** Investors
	[REDACTED]
"H Share(s)"	overseas **[REDACTED]** foreign Share(s) in the share capital of our Company with a nominal value of RMB1.00 each, which are to be **[REDACTED]** on the Stock Exchange and traded in Hong Kong dollars
"Hainan Wensen"	Hainan Wensen Foreign Trade Investment Partnership (Limited Partnership) (海南文森進出口貿易合伙企業(有限合伙)) (formerly known as Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙))), a limited partnership established in the PRC on January 5, 2021 and one of our Pre-**[REDACTED]** Investors
"HK$" or "Hong Kong dollar(s)"	Hong Kong dollar(s), the lawful currency of Hong Kong

[**REDACTED**]

"Hong Kong" or "HK"	the Hong Kong Special Administrative Region of the PRC

[**REDACTED**]

"IFRS"	International Financial Reporting Standards
"Independent Third Party(ies)"	person(s) or company(ies) who/which, to the best of our Directors' knowledge, information and belief, having made all reasonable enquiries, is/are not connected with our Company or our connected persons

[**REDACTED**]

"Jerei"	Shandong Jerei Digital Technology Co., Ltd.* (山東捷瑞數字科技股份有限公司), one of our collaborators and an Independent Third Party

[**REDACTED**]

"Joint Sponsors"	UBS Securities Hong Kong Limited and Essence Corporate Finance (Hong Kong) Limited
"Latest Practicable Date"	November 20, 2022, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

[**REDACTED**]

"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented from time to time
"Luye Group"	Luye Pharma and its subsidiaries which, for the purpose of this document and unless the context otherwise requires, excludes our Group
"Luye HK"	Luye Pharma Hong Kong Limited, a company incorporated with limited liability in Hong Kong and one of our Controlling Shareholders
"Luye Pharma"	Luye Pharma Group Ltd. (绿叶制药集团有限公司), an exempted company incorporated with limited liability in Bermuda on July 2, 2003 whose shares are listed on the Main Board of the Stock Exchange (stock code: 2186), and one of our Controlling Shareholders
"Luye Pharma Shareholder(s)"	holders of the Luye Pharma Shares
"Luye Pharma Shares"	shares of a par value of US$0.02 each in the share capital of Luye Pharma
"Main Board"	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange
"MOFCOM" or "Ministry of Commerce"	the Ministry of Commerce of the PRC (中華人民共和國商務部)

"Nanjing Ruiyuan"	Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)), a limited partnership established in the PRC on October 30, 2020 and one of our Pre-[**REDACTED**] Investors
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局)

[**REDACTED**]

"NPC"	the National People's Congress (全國人民代表大會)
"OcuMension"	OcuMension Therapeutics (Zhejiang) Co., Ltd.* (歐康維視(浙江)醫藥有限公司), one of our collaborators and an Independent Third Party

[**REDACTED**]

[REDACTED]

"PBOC"	the People's Bank of China (中國人民銀行), the central bank of the PRC
"PCT"	the Patent Cooperation Treaty, which assists applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions
"PRC" or "Mainland China" or "China"	People's Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires otherwise, references in this document to "China" and the "PRC" do not apply to Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan
"PRC Company Law"	the Company Law of the People's Republic of China (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time
"PRC Legal Adviser"	Commerce & Finance Law Offices, our legal adviser as to PRC laws
"Pre-[**REDACTED**] Investment(s)"	the pre-[**REDACTED**] investment(s) in our Company, the details of which are set out in the section headed "Pre-[**REDACTED**] Investments" in this document

"Pre-[**REDACTED**] Investor(s)"	the investor(s) of the Pre-[**REDACTED**] Investments, namely, Advantech Capital, SIP Sungent, CCB Juyuan, SD Jiazhi LP, SZ BioResearch, Qianhai Equity Fund, Serendipity Investment, Starr International, Brill Aimei, Yantai Blue Ocean, GTJA Huike, Yunnan Felix, Zhongyuan Qianhai, Brill Luoyi, Qianhai Weiyang, Yantai Bohui, Hainan Wensen, Yantai Innovative, Nanjing Ruiyuan, SZ Xingrui and Asian Alliance, the details of which are set out in the section headed "Pre-[**REDACTED**] Investments" in this document

[**REDACTED**]

"Qianhai Equity Fund"	Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合伙)), a limited partnership established in the PRC on December 11, 2015 and one of our Pre-[**REDACTED**] Investors
"Qianhai Weiyang"	Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)), a limited partnership established in the PRC on January 25, 2016 and one of our Pre-[**REDACTED**] Investors
"Qualified Institutional Buyer" or "QIB"	a qualified institutional buyer within the meaning of Rule 144A

[**REDACTED**]

"R&D"	research and development

[**REDACTED**]

"Remuneration Committee"	the remuneration committee of the Board

[**REDACTED**]

"RMB" or "Renminbi"	Renminbi, the lawful currency of the PRC

[**REDACTED**]

"S$" or "Singapore dollar(s)"	Singapore dollar(s), the lawful currency of Singapore
"SAFE"	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
"SD Jiazhi LP"	Shandong Growth Drivers Jiazhi Asset Investment Fund Partnership (Limited Partnership) (山東動能嘉智產業投資基金合伙企業(有限合伙)), a limited partnership established in the PRC on November 23, 2021 and owned as to 0.2% by Shandong New Growth Drivers Private Fund Management Co., Ltd. (山東省新動能私募基金管理有限公司) and 99.8% by Shandong New Growth Jiayuan Pioneer Investment Partnership (Limited Partnership) (山東動能嘉元創業投資基金合伙企業(有限合伙)), a fund controlled as to approximately 93.33% by SD New Growth, one of our Pre-[**REDACTED**] Investors
"SD New Growth"	Shandong New Growth Drivers Fund Management Co., Limited (山東省新動能基金管理有限公司), a company established in the PRC on April 9, 2018 and one of our Pre-[**REDACTED**] Investors

"Serendipity Investment"	Serendipity Investment (Hong Kong) Limited (天緣投資(香港)有限公司), a company incorporated with limited liability in Hong Kong on August 14, 2019 and one of our Pre-**[REDACTED]** Investors
"SFC"	the Securities and Futures Commission of Hong Kong
"SFO"	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Shandong Luye"	Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), a company established in the PRC on June 8, 1994 and one of our Controlling Shareholders
"Share(s)"	ordinary share(s) with nominal value of RMB1.00 each in the share capital of our Company
"Shareholder(s)"	holder(s) of our Share(s)
"SIP Sungent"	SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)), a limited partnership established in the PRC on January 16, 2019 and one of our Pre-**[REDACTED]** Investors
"Sophisticated Investor(s)"	has the meaning ascribed to it under Guidance Letter HKEX-GL92-18 issued by the Stock Exchange
	[REDACTED]
"sq.m."	square meters
	[REDACTED]
"STA"	the State Taxation Administration of the PRC (中華人民共和國國家税務總局)
	[REDACTED]

"Starr International"	Starr International Investments HK V, Limited, a company incorporated with limited liability in Hong Kong on November 20, 2015 and one of our Pre-[**REDACTED**] Investors
	[**REDACTED**]
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"Strategy Committee"	the strategy committee of the Board
"subsidiary(ies)"	has the meaning ascribed to it under the Listing Rules
"substantial shareholder(s)"	has the meaning ascribed to it under the Listing Rules
"Supervisor(s)"	the supervisor(s) of our Company
"SZ BioResearch"	Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), a limited partnership established in the PRC on August 20, 2020 and one of our Pre-[**REDACTED**] Investors
"SZ Xingrui"	Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)), a limited partnership established in the PRC on January 25, 2019 and one of our Pre-[**REDACTED**] Investors
"Takeovers Code"	The Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time
"Track Record Period"	the period comprising the two financial years ended December 31, 2020 and 2021 and the six months ended June 30, 2022
"U.S." or "United States"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"U.S. Securities Act"	United States Securities Act of 1933, as amended

[**REDACTED**]

"USPTO"	the United States Patent and Trademark Office
"US$" or "U.S. dollar(s)"	U.S. dollar(s), the lawful currency of the United States
"VAT"	value-added tax; all amounts are exclusive of VAT in this document except where indicated otherwise

[**REDACTED**]

"Yantai Blue Ocean"	Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資有限公司), a company established in the PRC on December 15, 2011 and one of our Pre-[**REDACTED**] Investors
"Yantai Bofa"	Yantai Bofa Investment Center Limited Partnership (煙台博發投資中心(有限合伙)), a limited partnership established in the PRC on September 10, 2020 and one of the ESOP Entities
"Yantai Bohui"	Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)), a limited partnership established in the PRC on January 6, 2021 and one of our Pre-[**REDACTED**] Investors
"Yantai Bolian"	Yantai Bolian Investment Center Limited Partnership (煙台博聯投資中心(有限合伙)), a limited partnership established in the PRC on September 10, 2020 and one of the ESOP Entities
"Yantai Bosheng"	Yantai Bosheng Investment Center Limited Partnership (煙台博晟投資中心(有限合伙)), a limited partnership established in the PRC on September 17, 2020 and one of the ESOP Entities

"Yantai Innovative"	Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)), a limited partnership established in the PRC on September 30, 2018 and one of our Pre-[**REDACTED**] Investors
"Yantai Luye"	Yantai Luye Pharmaceutical Holdings Co., Ltd. (煙台綠葉醫藥控股(集團)有限公司), a company established in the PRC on May 15, 2014 and one of our Controlling Shareholders
"Yunnan Felix"	Yunnan Felix Equity Investment Fund Management Partnership (Limited Partnership) (雲南菲利克斯股權投資基金管理合伙企業(有限合伙)), a limited partnership established in the PRC on February 24, 2021 and one of our Pre-[**REDACTED**] Investors
"Zhongyuan Qianhai"	Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)), a limited partnership established in the PRC on November 20, 2018 and one of our Pre-[**REDACTED**] Investors
"%"	per cent

In this document, unless expressly stated or the context requires otherwise:

- *all information and data is at the Latest Practicable Date;*
- *certain amounts and percentage figures, including but not limited to, shareholdings and operating data, may have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them;*
- *all references to any shareholdings in our Company assume no exercise of the* **[REDACTED]** *unless otherwise specified;*
- *references to "provinces" of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous region; and*
- *the names of Chinese laws and regulations, governmental authorities, institutions, natural persons or other entities (including certain of our subsidiaries) have been included in the document in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail. English translations of company names and other terms from the Chinese language are provided for identification purposes only.*

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain terms used in this document in connection with us and our business. Some of these may not correspond to standard industry definitions.

"%AUC_{ex}"	percentage of $AUC_{0-\infty}$ obtained by extrapolation
"5-FU"	5-fluorouracil
"ACE2"	angiotensin converting enzyme 2, widely distributed in various human tissues
"ADA"	anti-drug antibody
"ADC"	antibody-drug conjugates
"ADE"	antibody-dependent enhancement
"ADCC"	antibody-dependent cellular cytotoxicity
"ADRs"	adverse drug reactions
"AE(s)"	adverse event(s), any untoward medical occurrence associated with the use of a drug in human, whether or not considered drug related
"AESI"	adverse events of special interest
"ALK"	anaplastic lymphoma kinase
"assay(s)"	an analysis done to determine (1) the presence of a substance and the amount of that substance and (2) the biological or pharmacological potency of a drug
"AUC"	area under the drug concentration-time curve
"AUC_{0-t}"	area under the concentration-time curve from the first time point measured (0) to the last time point measured (t)
"AUC_{0-last}"	area under the concentration-time curve from 0 to the last quantifiable concentration time point
"$AUC_{\%Extrap}$"	the percentage of area under extrapolated concentration-time curve
"$AUEC_{0-t}$"	area under the effect-time curve from time 0 to time t

GLOSSARY OF TECHNICAL TERMS

"BALP"	bone alkaline phosphatase
"BCVA"	best corrected visual acuity
"BIAM"	Biosimilar Initial Advisory Meeting
"bioequivalence"	the absence of a significant difference in the rate and extent to which the active ingredient or active molecular portion in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered
"bioequivalents"	drugs having the equivalent bioavailability, i.e. the equivalent rates and extents of absorption of parent drugs or active metabolites from a dosage form into the systemic circulation
"Biosimilar Guidelines"	Technical Guideline for the Research, Development and Evaluation of Biosimilars (Tentative)
"biosimilars"	biological drugs which are designed to have the same amino acid sequence and the equivalent (but not identical or clinical better) active properties as compared to, and which are not necessarily clinically interchangeable with, reference drugs that have already received marketing approvals, not to be confused with such other terms as "biobetters" (which are clinically better than reference drugs), "biogenerics" (which are clinically interchangeable with reference drugs) or "follow-on biologics" (which may or may not include biosimilars) even though these terms are used interchangeably under certain regulatory regimes and in certain contexts
"BLA"	biologic license application
"BLI"	biolayer interferometry
"BMD"	bone mineral density
"BOIN"	Bayesian optimal interval
"BPD"	biological product development

"C1q"	complement component 1q, the first subcomponent of the C1 complex of the classical pathway of complement activation, which is a part of innate immune system
"cAMP"	cyclic adenosine monophosphate
"CD"	circular dichroism
"CD3"	a protein complex and T cell co-receptor that are involved in activating both cytotoxic T cell and its helper cells. It is composed of four distinct chains. In mammals, the complex contains a CD3γ chain, a CD3δ chain, and two CD3ε chains
"CD16a"	Fc receptors FcγRIIIa
"CD25"	α chain of the high-affinity IL-2 receptor that is encoded by the IL2RA gene
"CD32b"	an inhibitory surface receptor that is part of a large population of B cell co-receptors, which act to modulate signaling
"CD122"	subunit β of human IL-2 receptor that is encoded by the IL2RB gene
"CD132"	the common γ chain (CD132) that is a subunit of the interleukin (IL) receptors for IL-2, IL-4, IL-7, IL-9, IL-15 and IL-21
"CDC"	complement-dependent cytotoxicity
"CDMO"	contract development and manufacturing organization
"CE"	capillary electrophoresis
"CEA"	carcinoembryonic antigen (CEA), also known as carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5)
"CEACAM5"	carcinoembryonic antigen-related cell adhesion molecule 5

"cell line"	a population of cells which descend from a single cell and contain the same genetic makeup, thereby producing the same proteins. The productivity of a cell line determines the cost of manufacturing and the quality of a cell line is directly related to the quality of the relevant biologics
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"cHL"	classical hodgkin lymphoma
"CHMP"	Committee for Medicinal Products for Human Use
"CHO cells"	an epithelial cell line derived from the ovary of the Chinese hamster, often used in biological and medical research and commercially in the production of recombinant therapeutic proteins
"CI"	confidence interval
"cisplatin"	a class of chemotherapy medication used to treat a number of cancers
"CL"	clearance
"CL/F"	apparent total body clearance
"CL_z/F"	apparent clearance
"C_{max}"	maximum measured drug concentration
"CMC"	chemistry, manufacturing and controls processes in the development, licensure, manufacturing and ongoing marketing of pharmaceutical products
"CNV"	choroidal neovascularization
"combination therapy"	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
"COPD"	chronic obstructive pulmonary disease
"CPS"	combined positive score

GLOSSARY OF TECHNICAL TERMS

"CPT"	camptothecin, a topoisomerase inhibitor
"CQAs"	critical quality attributes
"CRC"	colorectal cancer
"CRO"	contract research organization
"CRS"	cytokine release syndrome
"CSCO"	Chinese Society of Clinical Oncology
"CT"	cycle threshold
"CTA"	clinical trial application
"C-terminal"	end of an amino acid chain (protein or polypeptide), terminated by a free carboxyl group (-COOH)
"CTX"	C-telopeptide
"CTX-1"	type I C-telopeptide
"cytokine"	a broad and loose category of small proteins that are important in cell signaling. Their release has an effect on the behavior of cells around them
"cytotoxic"	toxic to living cells
"DCR"	disease control rate
"DLT"	dose limiting toxicity
"DME"	diabetic macular edema
"DoR"	duration of response
"DPP-4"	Dipeptidyl peptidase-4, also known as adenosine deaminase complexing protein 2 or CD26 (cluster of differentiation 26) is a protein that, in humans, is encoded by the DPP4 gene
"DR"	diabetic retinopathy
"DSC"	differential scanning calorimetry
"ECG"	electrocardiogram

GLOSSARY OF TECHNICAL TERMS

"E_{max}"	maximal effect
"EGFR"	epidermal growth factor receptor
"ELISA"	enzyme-linked immuno sorbent assay
"ETDRS"	early treatment of diabetic retinal study
"endothelial cells"	a thin layer of simple, or single-layered, squamous cells that line the interior surface of blood vessels and lymphatic vessels, forming an interface between circulating blood or lymph in the lumen and the rest of the vessel wall
"FALA"	the Phe234Ala/Leu235Ala mutation in IgG4
"FAS"	full analysis set
"Fc"	fragment, crystallizable
"Fcγ receptors"	key immune receptors responsible for the effective control of both humoral and innate immunity and are central to maintaining the balance between generating appropriate responses to infection and preventing autoimmunity
"Fc region"	fragment crystallizable region, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
"FcRn"	a protein that in humans is encoded by the FCGRT gene
"first-line"	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment of a given type and stage of cancer. It is also called primary treatment or therapy
"FOLFOX"	a chemotherapy regimen for treatment of colorectal cancer, made up of the drugs folinic acid, fluorouracil, and oxaliplatin
"FTIR"	fourier transform infrared spectroscopy
"Fully human"	antibodies are developed with human antibody genes rather than mice genes

GLOSSARY OF TECHNICAL TERMS

"GC-MS"	gas chromatography-mass spectrometry
"GCP"	good clinical practice
"GCTB"	giant cell tumor of bone
"glioblastoma"	tumors that arise from astrocytes
"GLP"	good laboratory practice
"GLP-1"	glucagon-like peptide-1
"GLP-1R"	The glucagon-like peptide-1 receptor is a receptor protein found on beta cells of the pancreas and on neurons of the brain. It is involved in the control of blood glucose level by enhancing insulin secretion. In humans, it is synthesized by the gene GLP1R, which is present on chromosome 6
"GMP"	good manufacturing practice
"GMR"	geometric mean ratio
"Grade"	term used to refer to the severity of adverse events, using Grade 1, Grade 2, Grade 3, etc.
"GSP"	Good Supply Practice
"hACE2"	human angiotensin-converting enzyme 2
"HbA1c"	a form of hemoglobin that is chemically linked to a sugar. Most monosaccharides, including glucose, galactose and fructose, spontaneously bond with hemoglobin, when present in the bloodstream of humans
"HCC"	hepatocellular carcinoma
"HER2"	human epidermal growth factor receptor 2
"HTRF"	homogeneous time-resolved fluorescence
"HNSCC"	head and neck squamous cell carcinoma
"HPLC"	high-performance liquid chromatography
"HPV"	human papillomvirus

"HR1"	the heptad repeat 1 region in SARS-CoV-2 Spike
"HR2"	the heptad repeat 2 region in SARS-CoV-2 Spike
"HuMAb"	human monoclonal antibody
"IARC"	International Agency for Research on Cancer
"ICF"	Informed Consent Form
"ICH"	International Council for Harmonization
"icIEF"	imaged capillary isoelectric focusing
"ICP-MS"	inductively coupled plasma mass spectrometry
"IgG1 Fc"	a dimeric protein that mediates important antibody effector functions by interacting with Fcγ receptors (FcγRs) and the neonatal Fc receptor (FcRn)
"IgG2"	human immunoglobulin G2
"IgG4"	human immunoglobulin G4
"IL-2"	interleukin-2 (IL-2) is a type of cytokine signaling molecule in the immune system. It is a protein that regulates the activities of white blood cells that are responsible for immunity
"IL-2Ra"	interleukin-2 receptor alpha
"IL-4R"	Interleukin 4 Receptor
"immunogenicity"	the ability of a particular substance, such as an antigen or epitope, to provoke an immune response in human body and other animals (i.e., the ability to induce humoral and/or cell-mediated immune responses)
"immunotherapy"	use of the immune system to treat disease
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China
"IRB"	institutional review board

GLOSSARY OF TECHNICAL TERMS

"IRRC"	independent radiological review committees
"ITT"	intention-to-treat
"LC-MS"	liquid chromatography-mass spectrometry
"LSM"	least squares mean
"λ_z"	elimination rate constant
"MAA"	marketing authorization applications
"mAbs"	monoclonal antibodies
"MAPK pathway"	The mitogen-activated protein kinase (MAPK) cascade is a highly conserved module that is involved in various cellular functions, including cell proliferation, differentiation and migration. MAPK pathway is a chain of proteins in the cell that communicates a signal from a receptor on the cell surface to the DNA in the nucleus of the cell.
"mCRC"	metastatic colorectal cancer
"melanoma"	a form of skin cancer that arises when pigment-producing cells — known as melanocytes — mutate and become cancerous
"metastatic"	in reference to any disease, including cancer, disease-producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
"monotherapy"	therapy that uses a single drug to treat a disease or condition
"MRT_{0-t}"	mean residence time from 0 to t (time to detectable minimum drug concentration)
"$MRT_{0-\infty}$"	mean residence time from 0 extrapolated to infinity
"NAb"	neutralizing antibody
"NCCN"	National Comprehensive Cancer Network

"NOAEL"	no observed adverse effect level
"NRDL"	China's National Reimbursement Drug List
"NSCLC"	non-small cell lung cancer
"N-terminal"	the start of a protein or polypeptide referring to the free amine group ($-NH_2$) located at the end of a polypeptide
"OD"	optical density
"OPG"	osteoprotegerin
"ORR"	objective response rate
"OS"	overall survival
"P1NP"	procollagen-1 N-terminal peptide, a peptide formed during type 1 collagen synthesis, and its serum concentration is an index of the rate of bone turnover
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages. The normal function of PD-1 is to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T cell turns off its ability to kill the cell
"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"PD-L2"	PD-1 ligand 2
"PEI"	Paul-Ehrlich-Institut in Germany, a German national institute under the supervision of the German Ministry of Health
"PFS"	progression-free survival
"pharmacodynamics" or "PD"	the study of how drugs affect human body

"pharmacokinetics" or "PK"	the study of how human body acting on drugs, that is, ADME (absorption, distribution, metabolism and excretion)
"PI"	principal investigator
"PLGF"	placental growth factor
"PPS"	per-protocol sets
"PQAs"	product quality attributes
"pre-filled product"	a disposable product that is already loaded with the pharmaceutical substance to be given
"Q2W"	once every 2 weeks
"RANK"	receptor of RANKL
"RANKL"	receptor activator of nuclear factor kappa-b ligand
"RBD"	receptor-binding domain
"RCC"	kidney cancer, the symptoms for which may include blood in the urine (haematuria), low back pain on one side (not caused by injury), a mass (lump) on the side or lower back, fatigue (tiredness), loss of appetite, weight loss not caused by dieting, and/or a fever that is not caused by an infection and that does not go away
"RNA"	ribonucleic acid, a nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins, although in some viruses RNA rather than DNA carries the genetic information
"reference drugs" or "reference products"	a standardized substance or approved drug which is used as a measurement base for biosimilar drug candidates
"RVO"	retinal vein occlusion
"S1 subunit"	contains a receptor-binding domain (RBD) that recognizes and binds to the host receptor angiotensin-converting enzyme 2 (ACE2)

"S2 subunit"	composed successively of a FP, HR1, HR2, TM domain, and cytoplasmic domain fusion (CT), and responsible for viral fusion and entry
"SAEs"	serious adverse events
"SARS-CoV-2"	severe acute respiratory syndrome coronavirus 2
"ScFv"	single chain fragment variable
"SCLC"	small-cell lung cancer
"S-CTX"	serum type 1 C-telopeptide
"second-line"	with respect to any disease, such as "second-line squamous NSCLC", "second-line NSCLC" and "second-line melanoma", the therapy or therapies that are tried when the first-line treatments do not work adequately. The management of a cancer case requires regular evaluation of treatment and adjustment as needed. A break with the primary treatment and an adoption of a new regimen signals "second-line treatment." The first-line therapy may not have worked, may have had some limited efficacy, or may have produced unacceptable side effects, damaged organs in the body, or jeopardized the patient's life. Sometimes first-line therapies show progress for a period of time followed by a stalling or continued growth of the cancer. Often, the FDA, the NMPA or other drug regulatory authority will specifically approve a new drug for second-line therapy. This labeling is common for new drugs that treat cancer patients who have already received first-line therapy
"serious adverse events" or "SAEs"	any untoward medical occurrence in a patient during clinical trials that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect

"solid tumor"	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are sarcomas, carcinomas, and lymphomas
"SPR"	surface plasmon resonance
"S protein"	spike protein
"SRE"	skeletal-related events
"$t_{1/2}$"	terminal half-life
"T cell"	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
"TCR"	T cell receptor
"TEAE(s)"	treatment-emergent adverse event(s), which are adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
"TE_{max}"	time to reach maximum effect
"TGF-ß"	transforming growth factor ß
"t_{max}"	time to reach C_{max}
"toxicity"	the degree to which a substance or a mixture of substances can harm humans or animals. Acute toxicity involves harmful effects in an organism through a single or short-term exposure
"uCr"	urine creatinine
"uNTx"	urinary N-telopeptide
"V_d"	volume of distribution

"$V_{z/F}$"	apparent volume of distribution
"VEGF"	vascular endothelial growth factor
"VEGF-A"	vascular endothelial growth factor A
"VEGF-B"	vascular endothelial growth factor B
"VEGFRs"	VEGF receptors
"vial filing"	a process where pharmaceutical products, usually liquids, are packaged/filled into vials
"VISTA-DME"	study of intravitreal aflibercept injection in patients with diabetic macular edema
"wAMD"	wet age-related macular degeneration
"XELOX"	oxaliplatin and capecitabine
"ZDF"	Zucker diabetic fatty

FORWARD-LOOKING STATEMENTS

We have included in this document forward-looking statements. Statements that are not historical facts, including statements about our intentions, beliefs, expectations or predictions for the future, are forward-looking statements.

This document contains certain forward-looking statements and information relating to our Company and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words "aim," "anticipate," "believe," "could," "expect," "going forward," "intend," "may," "ought to," "plan," "project," "seek," "should," "will," "would" and the negative of these words and other similar expressions, as they relate to our Group or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing our company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- the timing of initiation and completion, and the progress of our research and development programs and clinical trials;
- the timing and likelihood of regulatory filings and approvals, and pricing of our product candidates;
- the commercialization of our product candidates;
- the market opportunities and competitive landscape of our product candidates;
- estimates of our costs, expenses, future revenues, capital expenditures and our needs for additional financing;
- our ability to attract and retain senior management and key employees;
- our operations and business prospects;
- future developments, trends, conditions and competitive landscape in the industry and markets in which we operate;
- our strategies, plans, objectives and goals and our ability to successfully implement these strategies, plans, objectives and goals;
- our ability to continue to maintain our market position in the PRC and global biologics industry;

- our financial condition and operating results and performance;
- industry trends and competition;
- our ability to attract customers and build our brand image;
- general political and economic conditions;
- changes to regulatory and operating conditions in the industry and markets in which we operate;
- our dividend policy; and
- the amount of, and potential for, future development of our business.

Subject to the requirements of applicable laws, rules and regulations, we do not have any and undertake no obligation to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. As a result of these and other risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect or at all. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to the cautionary statements in this section.

In this document, statements of or references to our intentions or those of our Directors are made as of the date of this document. Any such information may change in light of future developments.

An investment in the H Shares involves a high degree of risk. Prospective investors should carefully consider the following risk factors, together with all other information contained in the document, before deciding whether to invest in the H Shares. If any of the following events occur or if these risks or any additional risks not currently known to our Company or which it now deems immaterial risks materialize, the business, financial condition, results of operations and/or the ability of our Company to meet its financial obligations could be materially and adversely affected. The market price of the H Shares could fall significantly due to any of these events or risks (or such additional risks) and you may lose your investment.

RISKS RELATING TO THE DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVAL OF OUR DRUG CANDIDATES

We may not achieve favorable results for our drug candidates in clinical trials, and cannot give any assurance that any of our drug candidates currently in development will receive regulatory approval, which could hinder or halt their development.

Many of our drug candidates are currently in development. As of the Latest Practicable Date, we were developing eight innovative antibody drug candidates and five biosimilar drug candidates in our pipeline. Our ability to generate revenue is dependent on obtaining regulatory approval for and successfully commercializing such drug candidates, which may never occur. The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly, with no assured outcome. Since our inception and up to the Latest Practicable Date, we have commercialized only one product, Boyounuo® (BA1101), and we cannot assure you that we will be able to generate substantial revenue from the sales of Boyounuo® (BA1101). In addition, we cannot assure you that we will be able to obtain approval for any of our other drug candidates, or that any of such drug candidates will be successfully commercialized if we receive regulatory approval.

In China, where most of our drug candidate development activities are located, we must first obtain regulatory approval from the NMPA before we can proceed to commercialize our drug candidates. Similarly, we cannot commercialize drug candidates in the United States, the European Union or other jurisdictions outside of China without obtaining regulatory approval from the FDA, EMA or other relevant foreign regulatory authorities. Regulatory authorities, such as the NMPA, FDA and EMA, impose comprehensive and stringent review procedures in respect of drug candidates and activities associated with their development and commercialization, including, but not limited to, design, testing, manufacturing process, safety, efficacy, quality control and assurance, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export. The process of obtaining regulatory approvals in China, the United States, Europe and other countries is expensive, may take many years especially if additional clinical trials are required and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. As of the Latest Practicable Date, we have received the NMPA approvals, which permitted us to commence commercialization, for only two products, Boyounuo®

(BA1101) and Boyoubei® (BA6101). Even if we are able to file BLAs for our other drug candidates, our drug candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the NMPA, FDA, EMA or other relevant regulatory authorities regarding the design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the NMPA, FDA, EMA or other relevant regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- failure of contract research organizations ("**CROs**"), contract development and manufacturing organization ("**CDMO**"), clinical study sites or investigators to comply with the good clinical practice ("**GCP**") requirements imposed by the NMPA, FDA, EMA or other relevant regulatory authorities;
- failure of the clinical trial results to meet the level of statistical significance required by the NMPA, FDA, EMA or other relevant regulatory authorities for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the NMPA, FDA, EMA or other relevant regulatory authorities disagreeing with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of a new drug application or other submission or to obtain regulatory approval in China, the U.S. or elsewhere;
- the NMPA, FDA, EMA or other relevant regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the NMPA, FDA, EMA or other relevant regulatory authorities rendering our clinical data insufficient for approval;
- the NMPA, FDA, EMA or other relevant regulatory authorities restricting the use of our products to a narrow population; and
- our CROs, principal investigators ("**PIs**"), hospitals or licensors taking actions that materially and adversely impact the clinical trials.

Any unfavorable occurrences in respect of the above, such as findings that our drug candidates are potentially unsafe for human use, that data is inadequate to support a conclusion of effective treatment, or that there are any other characteristics that may preclude regulatory approval or prevent or limit commercial use, would present

significant obstacles to regulatory approvals or require us to cease any further development of such products. Moreover, given the lengthy approval process, any changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted BLA, pre-market approval or equivalent application, may also cause delays in the approval or rejection of an application. We would face significant difficulty of recovering the time and cost invested in such development, if at all, which could harm our financial prospects as well as our reputation among business partners, potential customers and prospective talents.

In addition, clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions, and obtaining regulatory approval in one jurisdiction does not mean that regulatory approval will be obtained, or will be more likely to be obtained, in any other jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. As a result, regardless of whether our drug candidates have successfully completed clinical trials, we cannot assure you that such success can be replicated in any other jurisdiction where we seek to commercialize such drug candidates. In addition, assuming that our clinical stage drug candidates are approved and commercialized, any safety issues, product recalls or other incidents related to drugs approved and marketed in one jurisdiction may adversely impact approval of those drugs by the relevant regulators in other jurisdictions. If we are unable to obtain regulatory approval for our clinical stage drug candidates in one or more jurisdictions, or any approval contains significant limitations, or are imposed on certain drug candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

Furthermore, even if we were to obtain regulatory approval of any clinical stage drug candidates, regulatory authorities may revoke approval, approve any of our drug candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of post-marketing clinical trials, or may approve a drug candidate with a label narrower than what we desire. The NMPA, FDA, EMA and other relevant regulatory authorities in other jurisdictions have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

We cannot assure you that any of our drug candidates will successfully progress through the drug development process or become a commercially viable drug and any such failure could have a material adverse effect on our business, prospects, financial condition and results of operations.

Clinical development involves a lengthy and expensive process with no assured outcome.

Clinical trials are expensive and difficult to design and implement and can take many years to complete. As of the Latest Practicable Date, we had a total of 13 drug candidates, 11 of which had entered or completed clinical trials or received the IND approvals from the CDE, comprising one drug candidate with BLA approved, three in Phase 3 clinical trial, one in Phase 2 clinical trial, four in Phase 1 clinical trial and two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU. While our clinical trial expenses for products in development may be capitalized in accordance with our accounting policies, expenditure on clinical trials recorded in our consolidated statements of profit or loss and other comprehensive income still constituted a significant portion of our R&D expenditure during the Track Record Period. Our research and development costs amounted to RMB236.3 million and RMB231.6 million for the years ended December 31, 2020 and 2021, respectively. Our research and development costs amounted to RMB111.6 million and RMB169.1 million for the six months ended June 30, 2021 and 2022, respectively.

Commencement of a clinical trial is subject to finalizing trial design based on ongoing discussions with the NMPA, FDA, EMA or other regulatory authorities. Successful completion of our clinical trials is a prerequisite to receiving BLA or similar approvals from the NMPA, FDA, EMA or other regulatory authorities for each drug candidate and, consequently, the ultimate commercialization of our drug candidates. We cannot assure you as to when the clinical trials for our drug candidates which have not yet commenced pre-clinical or clinical trials will begin, if at all. During the course of the drug development and clinical trial process, our drug candidates may fail for a variety of reasons. In particular, our drug candidates may not:

- be accepted by regulators as bioequivalent to the original biologics;
- offer enhanced therapeutic or other medical benefits over existing drugs or other drug candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future pre-clinical studies or clinical trials;
- produce meaningful clinical responses or the participants may be exposed to unacceptable health and safety risks;
- be free from adverse events, undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials;
- meet applicable regulatory standards; and
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost.

In addition, the NMPA, FDA, EMA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, change their position on the acceptability of trial designs or clinical endpoints, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials, in which case we may have difficulty adjusting our trials to comply with new developments that we did not initially expect, and which in any case could result in delays to the overall regulatory approval process.

We may encounter various delays in the preclinical programs, clinical development and regulatory approval process, which may result in delays in, or suspension of, the commercialization of our drug candidates.

We may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, future clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- the number of subjects required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;

- our drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, institutional review boards ("**IRBs**") or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical testing or clinical trials of other drugs or therapies that raise safety or efficacy concerns about our drug candidates;

- our third parties including collaborators may not successfully carry out their contractual duties or meet expected deadlines;

- regulators, IRBs or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites, CROs, PIs or hospitals who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites, PIs and hospitals;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon drug development programs;

- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- the ability to conduct a companion diagnostic test to identify subjects who are likely to benefit from our drug candidates;

- we may elect to, or regulators, IRBs or ethics committees may require that we suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks; and

- the cost of clinical trials of our drug candidates may be greater than we anticipate.

In addition, once clinical trials begin, we could encounter regulatory delays if such trial is suspended or terminated by us or, as applicable, the IRBs or ethics committee of the institutions in which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA, FDA, EMA or other regulatory authorities. Such authorities, or we in our own judgment, may impose a delay, suspension or termination of our trials due to a number of factors, including:

- unforeseen safety issues or adverse side effects;

- our inability to enroll or retain a sufficient number of subjects who meet the inclusion and exclusion criteria in a clinical trial;

- failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols;

- inspection of the clinical trial operations or trial site by the NMPA, FDA or other regulatory authorities that results in the imposition of a clinical hold;

- failure to demonstrate a benefit from using a drug;

- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial;

- our inability to obtain sufficient funds required for a clinical trial;

- regulatory requests for additional analyses, reports, data, pre-clinical studies and clinical trials;

- regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;

- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in jurisdictions that require such approvals;

- failure to reach agreement with the NMPA, FDA, EMA or other regulators regarding the scope or design of our clinical trials;

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;

- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;

- delay or failure in adding new clinical trial sites;

- ambiguous or negative interim results, or results that are inconsistent with earlier results;

- unfavorable or inconclusive results of clinical trials and supportive pre-clinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;

- feedback from the NMPA, FDA, EMA, IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent pre-clinical studies and clinical trials, that might require modification to the protocol;

- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;

- our inability to reach agreements on acceptable terms with prospective CROs, PIs, hospitals or trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different parties;

- our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;

- difficulty obtaining sufficient quantities of supplies from third parties in a timely manner; and

- difficulty in maintaining contact with subjects after treatment, resulting in incomplete data.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals, and we may run out of funding before a trial is complete, which could result in us having to delay or suspend the trial until sufficient funding is procured, or we would have to abandon developing of the drug candidate completely. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates. If we fail to achieve product development milestones as disclosed in this document, our business prospects might be adversely affected. Any of the above negative developments could have a material adverse effect on our business, financial condition and results of operations.

Successful results in earlier studies in the clinical development process may not be predictive of future trial results.

Even if our drug candidates demonstrate favorable results in pre-clinical studies and clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our drug candidates. In addition, the outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. We cannot assure you that any of our drug candidates, some of which have achieved favorable early stage pre-clinical and clinical trial results, will achieve similar success in later clinical trial stages or in post-clinical trials.

A number of companies in the pharmaceutical industry have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in pre-clinical testing or early-stage clinical trials. Accordingly, results from completed pre-clinical studies and early-stage clinical trials of our drug candidates may not be indicative of the results that we may obtain in later stage trials, where such drugs may fail to show the desired safety and

efficacy traits despite having progressed through pre-clinical studies and initial clinical trials with favorable outcomes. Such variability in safety and/or efficacy results may be caused by numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Results may also differ from earlier trials due to the larger number of clinical trial sites and potentially different countries and populations involved in such trials.

Furthermore, even if the data collected from pre-clinical studies and clinical trials involving one of our drug candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support a conclusion of receiving regulatory approval from the NMPA, FDA, EMA or other relevant regulatory authorities in other jurisdictions required to market and distribute the drug.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that are currently contemplated, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates, if at all;
- ultimately obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements;
- encounter difficulties in obtaining, or be unable to obtain, reimbursement for use of certain drugs;
- be subject to restrictions on the distribution and/or commercialization of drugs; and/or
- have the drug removed from the market after obtaining regulatory approval.

Any of the above developments could result in a material adverse effect on our business, financial condition and results of operations.

If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events, which could affect patient recruitment or the

ability of enrolled subjects to complete the trial, and result in potential product liability claims. In addition, our clinical trials may be shown to lack meaningful clinical response or other unexpected characteristics.

If the results of clinical trials of our drug candidates are not positive or only modestly positive for proposed indications or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates, or not obtain regulatory approval at all;
- be required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate;
- be required to add labelling statements, such as a "boxed" warning or a contraindication;
- be required to create a medication guide outlining the risks of the side effects for distribution to patients;
- be required to develop risk management plans to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- not obtain regulatory approval for all the proposed indications as intended;
- be subject to restrictions on how the drug is distributed or used;
- be sued or held liable for injury caused to individuals exposed to or taking our drug candidates; and
- be unable to obtain reimbursement for use of the drug.

If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, FDA, EMA or other relevant regulatory authorities.

Certain diseases may have relatively low prevalence, and it may be difficult to identify a sufficient number of eligible patients. In addition, some of our drug candidate trials may require enrolling patients who have failed their first or second-line treatments, which limits the total size of the subject population available for such trials. Subject enrollment may also be affected by factors such as:

- the severity of the disease under investigation;
- the total size and nature of the relevant subject population;
- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the subjects referral practices of physicians;
- the ability to obtain and maintain patient consent;
- the availability of competing therapies also undergoing clinical trials;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective subjects.

The inability to enroll a sufficient number of subjects for our clinical trials for any of the above reasons would result in significant delays, increased drug development costs and could even require us to abandon one or more clinical trials altogether. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates. Any of the above could result in a material adverse effect on our business, financial condition and results of operations.

We may not be successful in our efforts to identify, discover or license-in new drug candidates to build or maintain our product pipeline, or license-out our existing drug candidates.

We may fail to identify, discover or license-in new drug candidates for clinical development for a number of reasons. For example, with respect to identifying and discovering new drug candidates for development in-house, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and

disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. We may consider licensing-in promising drug candidates to add to our pipeline in the future. Regardless of whether we develop new drug candidates in-house or license-in, our R&D efforts may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or

- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates, develop suitable potential drug candidates through internal research programs, or successfully license-in drug candidates at favorable commercial terms or at all, any of which could materially adversely affect our future growth and prospects. Even if we are able to identify, discover or license-in the drug candidates that we target, we cannot assure you that the product will be successfully commercialized. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

Furthermore, we may license-out our existing drug candidates to other drug developers, or otherwise collaborate with third parties on our existing drug candidates. We cannot assure you that when we license-out drug candidates, we will successfully be able to do so, or that any such partner will be able to successfully promote or commercialize products licensed from us, which in turn could adversely affect the benefits that we may achieve from such arrangement. If we are unable to successfully identify a licensee partner for a particular drug candidate and are not able to further develop such drug candidate in-house, we may not be able to recover our investment in that product.

Even after we successfully license-in or license-out drug candidates, we cannot assure you that our licensors or licensees will not breach the relevant license agreements, whether inadvertently or otherwise. Alternatively, our licensors or licensees might conclude that we have materially breached our license agreements. In either case, the license agreements may be terminated, thereby stopping us from developing and commercializing the drug candidates we licensed-in or generate licensing fees and royalties from the drug candidates we licensed out.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on other drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

As we have limited human and financial resources, we must limit our research and development programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Such developments could have a material adverse effect on our business, financial condition and results of operations.

Our drug candidates may cause undesirable side effects or have other properties that could delay or preclude their further development or regulatory approval or could have significant negative consequences on our ability to market and distribute our drug candidates or maintain market acceptance of such drugs if commercialized.

As with most pharmaceutical products, the use of our drugs could be associated with side effects or adverse events. Such side effects or other adverse events may be observed at any time, including in clinical trials or after a product is commercialized. It is not uncommon in the biopharmaceutical industry for drug candidates which showed promise in early stage testing for treating cancer to have later been found to cause side effects that prevented further development of the drug candidate or resulted in significant negative consequences if the drug has already been commercialized. Moreover, because clinical trials assess a sample of the potential patient population, when such trials are conducted with a limited number of patients and duration of exposure, rare and severe side effects of our drug candidates may only be uncovered when a significantly larger number of patients become exposed to the drug candidate.

As several of our drug candidates are indicated for cancer treatment, they may cause or be associated with side effects such as fatigue, nausea and low blood cell levels, which are commonplace among oncology drugs generally, as well as encounter off-toxicity issues. However, a high and unacceptable severity and prevalence of these or other side effects arising in the course of our drug candidate clinical trials could make us, whether voluntarily or at the determination of the NMPA, FDA, EMA or any other relevant regulator or otherwise, perform additional studies, delay, suspend or terminate clinical trials or cease further development of such drug candidate and withdraw it from any or all targeted indications.

Even if we are able to proceed with continued development of a drug candidate, we cannot assure you that we will be able to resolve any product-related adverse effects to the satisfaction of the NMPA, FDA, EMA or any other relevant regulator in a timely manner or at all. Drug-related side effects could also affect subject recruitment for clinical trials or the ability of enrolled subjects to complete our current trials, or result in potential liability claims.

Additionally, even if one or more of our drug products or drug candidates receive marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw or limit approvals of such products;
- regulatory authorities may require additional warnings, contra-indications or other restrictions on the labels of such products;
- regulatory authorities may require us to develop risk evaluation and remediation or mitigation plans, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, restricted distribution methods, patient registries and/or other elements to assure safe use and minimize risk;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates;
- we may be required to recall such products and be sued and held liable for harm caused to patients, which could be costly and result in significant negative publicity; and
- our reputation may suffer.

Furthermore, regulatory agencies may require us to cross-report certain information about adverse medical events involving our drug candidates to relevant regulators in other jurisdictions within a specified time frame. If we fail to timely comply with such reporting obligations for any reason, we could be subject to disciplinary or other actions by such regulators, including criminal liability, civil penalties, product seizure and/or delays in approval or clearance of future drug candidates.

Any of the above negative developments could prevent us from achieving or maintaining regulatory approval or market acceptance of the affected drug candidates, as well as substantially increase the costs of commercializing our drug candidates even if approved, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Adverse drug reactions and negative results from off-label use of our products could materially harm our business reputation, product brand name, financial condition and expose us to liability.

Products distributed or sold in the biopharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, the FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains a risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including our Company's share price. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

We rely on third parties to conduct certain aspects of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed. If we lose our relationships with our third parties, our product or drug development efforts could be delayed.

As is common practice in our industry, we have engaged and plan to continue to engage third-party CROs, PIs and hospitals to monitor and manage data for some of our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials in certain respects that are not completely under our control. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

The staff of CROs, PIs and hospitals engaged by us are not our employees and we cannot control whether or not they devote sufficient time, resources and oversight to our ongoing pre-clinical studies and clinical programs. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, such as GCP, good laboratory practice ("**GLP**") and human and animal testing regulations, each of which may be applicable and enforced by the NMPA, FDA, EMA and/or other relevant regulatory authorities for drug candidates in development. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, investigators and trial sites, and the fact that we rely on CROs, PIs and hospitals to conduct our pre-clinical studies and clinical trials does not relieve us of our regulatory responsibilities. If we or any of our CROs, PIs or hospitals fail to comply with applicable GCP requirements, the data generated in the pre-clinical

studies and clinical trials may be deemed unreliable and the NMPA or comparable foreign regulatory authorities may require us to perform additional pre-clinical studies and clinical trials before approving our marketing applications. We cannot assure you that such regulatory authority will determine that any of our pre-clinical studies and clinical trials comply with all of their requirements, which in turn may require us to repeat such studies and trials, which would delay the regulatory approval process. If CROs, PIs or hospitals do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to applicable protocols, regulatory requirements or for other reasons, our pre-clinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. Any of the above could result in a material adverse effect on our business, financial condition and results of operations.

Switching or adding additional third-party service providers involves additional cost and requires management time and focus. Our third-party service providers may terminate their agreements with us in the event of an uncured material breach. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our R&D programs. In addition, there is a natural transition period when a new third-party service provider commences work and the new third-party service provider may not provide the same type or level of services as our original provider. If any of our relationships with our third-party service providers is terminated, we may not be able to enter into arrangements with alternative third-party service providers timely or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

Our future performance is dependent on our ability to work effectively with collaborators to develop our drug candidates, including obtaining regulatory approval, and our arrangements with these collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to (i) undertake R&D programs and conduct pre-clinical studies and clinical trials, (ii) manage or assist with the regulatory filings and approval process and (iii) assist with our commercialization efforts. For example, we granted OcuMension certain exclusive right to promote and commercialize BA9101 in China and OcuMension agreed to conduct the remaining Phase 3 clinical trial of BA9101 in China and bear the expense arising from the Phase 3 clinical trial. See "Business — Commercialization, sales, marketing and distribution — R&D partner and promoter". We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us.

To the extent that we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected and our product or drug development efforts could be delayed. Though we carefully manage our relationships with our third-party service providers, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our drug candidates.

We conduct a significant portion of our operations in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. For example, in China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. The Standing Committee of the National People's Congress promulgated the Decision of the Standing Committee of the National People's Congress on Revising the Patent Law of the People's Republic of China (2020) (effective from June 1, 2021), which introduces patent extensions to eligible innovative drug patents and patent term adjustment. Patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products without facing infringement risks. It may also enable the patent owner to submit applications for a patent term extension or enable CNIPA to adjust the patent term. The length of any such extension or adjustment is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on us. Changes in either the patent laws or their interpretation in China or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the benefits we believe are available to us from developing and manufacturing drugs in China.

The approval pathway for biosimilars in China remains fluid, which may adversely affect the regulatory approval of our biosimilar drug candidates.

The Technical Guideline for the Research, Development and Evaluation Biosimilars (Tentative) (the "**Biosimilar Guidelines**") issued by the NMPA on February 28, 2015, which are the prevailing PRC regulation on biosimilar evaluation and marketing approval, outline the regulatory framework for biosimilars, aiming to move toward a clear industry structure for the development of biosimilars. The Biosimilar Guidelines do not offer an alternative pathway for launching biosimilar products in China; rather, biosimilars are essentially subject to the same approval pathway as novel biologics, only with a different set of data requirements. Applicants must mark in their IND applications and BLAs that submissions are intended to be reviewed as biosimilars. In addition, various uncertainties surrounding the application and interpretation of the Biosimilars Guidelines could adversely affect the regulatory approval of our existing biosimilar drug candidates, including all of our Core Products, as well as certain other products in our pipeline and any other biosimilars we may develop in the future. Uncertainties surrounding the approval pathway for biosimilars in China include:

- the Biosimilar Guidelines serve as a technical guidance only and cannot address several fundamental issues for the administration of biosimilars in the absence of a clear legislative authorization, such as interchangeability with reference products, naming rules and labeling requirements for biosimilars;

- although the Biosimilar Guidelines adopt a stepwise comparability approach, they do not contain sufficient details to be regarded as overarching guidelines and it is also not clear whether the NMPA will take further steps to develop product-specific guidelines and guidelines addressing issues such as immunogenicity assessment;

- while under the Biosimilar Guidelines, biosimilars are subject to the same approval pathway as innovative biologics with a different set of technical review criteria, it remains unclear if the time to market for biosimilars will be reduced compared with the lengthy review process for innovative biologics; and

- since changes in regulatory requirements and guidance may occur, it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines on biosimilars to replace or supplement the Biosimilar Guidelines, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

As such, we cannot assure you that, aside from Boyounuo® (BA1101) and BA6101, our biosimilar candidates will be approved under the Biosimilar Guidelines or any further updated policies or guidelines in the future, in a timely manner or at all, and we may not ultimately be able to develop and market any or all of them successfully.

Even after we obtain regulatory approval for the marketing and distribution of our drug candidates, our products will continue to remain subject to regulatory scrutiny, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our drug candidates, we may be subject to penalties.

Assuming that our drug candidates receive regulatory approval, they will remain subject to ongoing regulatory requirements with respect to production, labeling, packaging, storage, distribution, advertising, promotion, approved uses, sampling, recordkeeping, conduct of post-marketing studies and submission of safety monitoring, efficacy and other post-market information, as set forth by the NMPA, FDA, EMA and any other relevant regulatory authorities. Our manufacturing facilities are similarly required to comply with such regulators, including in respect of ensuring that quality control and assurance and manufacturing procedures conform to current GMP practice. Moreover, any new legislation addressing drug safety issues could result in increased costs to ensure compliance with ongoing regulatory requirements. Continued monitoring and compliance obligations may also require us to, from time to time, submit new or supplemental applications to obtain approval for certain changes to approved drugs or the labeling or manufacturing process, which may entail conducting post or supplemental clinical trials at our own cost in order to refresh any regulatory approvals or expand the eligible patient population for our drug indications. Accordingly, we must continue to spend significant time and resources in various areas of regulatory compliance and be subject to continuing review and inspections to assess such compliance. We cannot assure you that we will be able to successfully comply with post-commercialization drug regulations or that we will be able to do so in a cost-effective manner. Any failure to do so could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR FINANCIAL PROSPECTS AND NEED FOR ADDITIONAL CAPITAL

We incurred net losses during the Track Record Period and we may continue to incur losses in the near future and may not achieve or maintain profitability. Investors are at risk of losing substantially all of their investments in our H Shares.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditure and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. As of the Latest Practicable Date, we had launched a biosimilar product commercially, namely Boyounuo® (BA1101), and we are developing eight innovative antibody drug candidates and five biosimilar drug candidates in our pipeline. However, we have incurred and continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses during the Track Record Period. For the years ended December 31, 2020 and 2021, we reported a net loss attributable to the owners of the parent of RMB240.5 million and RMB225.4 million, respectively. For the six months ended June 30, 2021 and 2022, we reported a net loss

attributable to the owners of the parent of RMB127.9 million and RMB153.3 million, respectively. We expect to continue to incur losses in the foreseeable future, and these losses may further increase as we:

- continue our development and commence clinical trials of our drug candidates;
- seek regulatory approvals for our drug candidates throughout the research and development and clinical trial stages;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- maintain and expand our manufacturing facilities;
- continue to increase clinical, operational, financial, manufacturing and scientific personnel;
- establish and expand our sales, marketing and commercialization infrastructure and workforce and maintain our sales network for any products that obtain regulatory approval;
- seek to identify additional drug candidates;
- address any competing technological and marketing developments, including new products developed by competitors;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend intellectual property-related claims; and
- acquire or in-license other intellectual property, drug candidates and technologies.

The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue, in particular from product sales, which will be affected if any of the drug candidates in our pipeline fails or experiences significant delay in commercialization for any reason. To become and remain profitable, we must develop and eventually commercialize drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our drug candidates, obtaining regulatory (such as INDs and BLAs) and marketing approval for these drug candidates, manufacturing, marketing and selling those drug candidates and satisfying any post-marketing requirements. Moreover, we have only commercialized Boyounuo® (BA1101) and we have a limited number of Core Products portfolio, each of which had entered or completed Phase 2 or 3 clinical trials as of the Latest Practicable Date. We are susceptible to the performance of Boyounuo® (BA1101) and our other drug candidates to be commercialized. If we are unable to achieve sufficient market acceptance or favorable

pricing for such products, our path to profitability, in terms of both feasibility and timing, would be further harmed, as well as our prospects of generating sufficient cash to fund the development of our other pipeline projects.

We cannot assure you that we will ever succeed in any or all of these activities and, even if we do, we may never generate sufficient revenues to break even or achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our Company also could cause you to lose all or part of your investment.

We had negative cash flow from operating activities throughout the Track Record Period and we will likely need substantial additional funding for our drug development programs and commercialization efforts, which may not be available on acceptable terms, or at all.

Our operations have consumed substantial amounts of cash since our inception. Although we started to sell Boyounuo® (BA1101) in May 2011 and recorded a revenue of RMB158.7 million for the year ended December 31, 2021 and RMB220.7 million for the six months ended June 30, 2022, we still have not generated positive net cash flow from operating activities. For the years ended December 31, 2020 and 2021, we recorded negative cash flow from operating activities of RMB506.7 million and RMB246.3 million, respectively. For the six months ended June 30, 2021 and 2022, we recorded negative cash flow from operating activities of RMB151.7 million and RMB114.2 million, respectively. To date, due to our negative operating cash flow, we have needed external financing throughout our operating history, which we have financed primarily through pre-[**REDACTED**] investments. We received a total amount of RMB1,087.5 million paid by our pre-[**REDACTED**] investors from two rounds of pre-[**REDACTED**] Investments for the years ended December 31, 2020 and 2021. See "Pre-[**REDACTED**] Investments" for further details. We also utilized external financing and related-party loans to provide part of our operating fund. For example, we had interest-bearing loans and borrowings of nil, RMB250.0 million and RMB251.7 million, respectively, as of December 31, 2020 and 2021 and June 30, 2022. We had related-party loans of RMB234.5 million, RMB13.0 million and RMB3.8 million as of December 31, 2020 and 2021 and June 30, 2022, respectively.

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our various clinical stage drug candidates, continue research and development of our pre-clinical stage drug candidates, initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates and expand our manufacturing capability. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;

- the cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;
- any cash received from commercial sales of any drug candidates for which we receive regulatory approval;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or license other drug candidates and technologies; and
- our headcount growth and associated costs.

Moreover, as we obtain regulatory approval for our clinical stage drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs required for the manufacture of any drug candidate that receives regulatory approval may be substantial. However, financing may be unavailable in amounts or on terms acceptable to us. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, the incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants restricting our operations or our ability to pay dividends, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We had substantial indebtedness and net current liabilities at certain points during the Track Record Period, and may continue to incur significant debt going forward.

We had interest-bearing loans of RMB251.7 million as of June 30, 2022. We also had net current liabilities of RMB304.1 million as of December 31, 2020, primarily attributable to due to related parties of RMB284.8 million.

A large balance of indebtedness, whether from banks or related parties, may require that we devote our financial resources to servicing such debt rather than funding our operating activities and investments in research and development, which constrains our capital flexibility and may in turn adversely affect our drug development timetable. It may also be a challenge for us to service our interest and principal repayments in a timely

manner or at all, which could trigger cross-defaults with other debt, as applicable, as well as limit our ability to obtain further debt financing. Given our historical reliance on external financing, such developments could have a material adverse effect on our business, financial condition and results of operations.

We have only recently begun commercializing one of our drug candidates, which may make it difficult to evaluate our future prospects.

We have just commenced commercial sales of our first product, Boyounuo® (BA1101), in May 2021. Except for the commercialization of Boyounuo® (BA1101), our operations have been limited to developing and undertaking pre-clinical studies and clinical trials of our drug candidates. Accordingly, our operating history, in particular period-to-period comparisons of our historical results of operations, may not be a reliable indicator of our future performance or serve as an adequate basis for evaluating our business prospects and financial performance. Similarly, our results of operations in some reporting periods may fall below market expectations, or experience significant fluctuations from period to period or within certain periods. Even if we are able to bring more products to market, we may not be able to expand our business and capture market share, maintain our competitive position, satisfy our contractual obligations, or sustain growth and profitability. As a result, any predictions about our future success or viability may not be accurate.

We have a large balance of intangible assets and we may incur significant impairment charges which could materially impact our financial position.

Our intangible assets primarily consist of (i) technology know-how mainly representing proprietary technology, (ii) software and (iii) deferred development costs mainly representing the expenditure incurred for our drug candidates which were capitalized. Our intangible assets amounted to RMB325.3 million, RMB566.0 million and RMB653.2 million as of December 31, 2020 and 2021 and June 30, 2022, respectively, and were among the largest components of our assets as of each such date. See note 15 to the Accountants' Report in Appendix I in this document for a breakdown of our intangible assets as of the end of each financial period during the Track Record Period. We measure intangible assets initially at cost and subsequently apply accumulated amortization and any impairment losses as they arise in regular testing. See "Financial Information — Critical accounting policies and estimates" for further details. While we did not recognize any substantial impairment loss for intangible assets during the Track Record Period, we cannot assure you that there will be no such charges in the future. In particular, the failure to generate financial results commensurate with our intangible assets estimates may adversely affect the recoverability of such intangible assets, and in turn result in impairment losses. As we carry a substantial balance of intangible assets, any significant impairment losses charged against our intangible assets could have a material adverse effect on our business, financial condition and results of operations.

We have granted, and may continue to grant, share incentives, which may result in increased share-based compensation expenses and diluted effect to our shareholders.

We established an employee share incentive plan with the aim to incentivize employees of our Group to remain with us, and to attract suitable personnel for our long-term growth. For the years ended December 31, 2020 and 2021 and six months ended June 30, 2021 and 2022, our share-based payment expenses were nil, RMB21.3 million, RMB7.1 million and RMB9.1 million, respectively. We account for compensation costs for all ESOP using a fair value-based method and recognize expenses in our consolidated statements of profit or loss in accordance with IFRSs.

We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we will continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations and financial conditions. In addition, our granting of share-based awards could dilute your interest in our Company.

RISKS RELATING TO THE COMMERCIALIZATION OF OUR DRUG CANDIDATES

Certain of our biosimilar products may not be as advanced in development as some of the equivalent biosimilar candidates being developed by our competitors, which may result in our competitors capturing significant first-entrant advantages with respect to their products.

Our biosimilar drug candidates face strong competition from other marketed drugs or drug candidates in the development stage. It is likely that these competitor candidates will ultimately be approved and commercialized before our candidates, which may enable them to capture significant first-entrant advantages in establishing market presence and brand awareness. This in turn could place our drug candidates at a major commercial disadvantage at the time of launch, from which we may not be able to recover. In particular, under the Prescription Management Regulation (《處方管理辦法》), PRC hospitals may not procure more than two drugs of the same generic name, which in practice means that for each generic drug, a hospital will only procure the reference drug and one biosimilar. Unlike new or innovative drugs, biosimilar candidates are approved based on their bioequivalence to the reference drugs, and as such, biosimilars to the same reference drug as developed by different companies are generally not expected to have meaningful differences in efficacy or safety compared to each other. Consequently, we do not expect to be able to compete and gain market shares from the first-entrant products on those bases. We may instead seek to compete on pricing or product quality and reliability (perceived or otherwise), which we may not be able to do successfully. As a result, even assuming that we are able to obtain regulatory approvals for our drug candidates, we cannot assure you that they will be able to achieve commercial success, whether due to established first-entrants or otherwise. This in turn could have a material adverse effect on our business, financial condition and results of operations.

We have only recently begun commercializing our drug products and have just started to generate revenue from product sales, and we cannot assure you that we will be able to generate substantial revenue in the future.

We have just commenced commercial sales of one product, Boyounuo® (BA1101), in May 2021. During the Track Record Period, we generated revenue solely from sales of Boyounuo® (BA1101) of RMB158.7 million for the year ended December 31, 2021 and RMB220.7 million for the six months ended June 30, 2022, which was insufficient to support our entire business operations. We may continue to have periods in the future where we generate little to no revenue from such sources. We will need to successfully bring more products to market and achieve market acceptance and commercial success with our existing and future products and drug candidates in order to generate substantial revenue from product sales, which we cannot assure you that we will be able to do.

In order to commercialize any of our drug candidates, we must first complete all requisite clinical trials and receive regulatory approval to commence production and sale. However, even after a drug candidate is eventually made available for sale, it may nonetheless fail to gain market acceptance from physicians, patients, third-party payors and others in the medical community. For example, several of our key drug candidates are designed to treat various cancers. However, current cancer treatments such as chemotherapy and radiation therapy are well established in oncology treatment and literature, and doctors may continue to rely on these treatments to the exclusion of our drug candidates, or prefer other novel oncology drugs and treatment options to our drug candidates. Other factors which may affect the degree of market acceptance of our drug candidates, if approved for commercial sale, include, among others:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the NMPA, FDA, EMA or other relevant regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, FDA, EMA or other relevant regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitor drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;

- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third party payors and government authorities;

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and

- the effectiveness of our sales and marketing efforts.

If our products fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue, in which case we may not be able to achieve a profit on such products or even be able to recoup our cumulative investment costs in such products. Moreover, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. For example, the originator companies may develop as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental application filed with the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biological product, it may capture a significant share of the originator product market in the applicable jurisdiction and thereby significantly reduce the market for our potential biosimilar drugs and drug candidates.

In addition, in China, each public medical institution has historically procured drugs through a provincial centralized drug purchase platform, and made substantially all of its purchases of pharmaceutical products through a centralized tender process. We plan to submit bids in a centralized tender process in the future to supply our Boyounuo® (BA1101) to these institutions at specified prices. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public hospitals and other medical institutions at the bid prices, which is the primary determinant of the prices at which we sell our Boyounuo® (BA1101) to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. In November 2018, the national pilot program for drug centralized procurement with minimum procurement quantities was launched in 11 cities in China, which was later expanded to other areas in September 2019. The bid-winning drugs under the regime will be procured by the public hospitals in the covered regions with priority, which will significantly boost their market shares and revenues. The centralized procurement regime requires the generic drugs to pass the QCE in order to participate in the centralized tendering. If we fail to acquire the QCE status, or we are unable to win in the bidding process for the centralized tender, our market share, revenues, and profitability may be adversely affected. For details, please refer to "Business — Commercialization, sales, marketing and distribution — Pricing" and "Regulatory Overview — Other laws and regulations in relation to medical industry — Regulations on centralized procurement".

Our sales volumes and profitability depend on our ability to successfully differentiate our Boyounuo® (BA1101) and price our bids in a manner that enables us to succeed in the bidding process at profitable levels. If we are unable to do so, we will lose the revenue associated with the sale of the Boyounuo® (BA1101) to the relevant hospitals and other medical institutions in China, which may have a material and adverse impact on our business, financial condition and results of operations. We may fail to win bids due to various factors, including reduced demand for the relevant product, uncompetitive bidding price, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, the relevant product is perceived to be less clinically effective than competing products or our services or other aspects of our operations are perceived to be less competitive. If our Boyounuo® (BA1101) is not selected in the bidding process in one or more regions, we will be unable to sell it to the hospitals and other medical institutions in those regions, and our market share, revenues and profitability could be adversely affected.

Even if we are able to commercialize any drug candidates, the drugs may become subject to national or other third-party reimbursement practices, healthcare reform initiatives or unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed, and the pricing review period may not begin until after marketing or licensing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. For example, centralized procurement in China has strong bargaining power over pricing of biopharmaceutical products. As a result, even if we are able to commercialize any drug candidates, the drugs may become subject to reimbursement practices, healthcare reform initiatives or unfavorable price regulations that may delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval.

Our ability to generate substantial revenue from our product or successfully commercialize any drug candidate also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

However, they may attempt to control costs by limiting coverage and the amount of reimbursement for particular medications, requesting that the drug companies provide discounts from list prices or challenging them on such prices. We cannot assure you that reimbursement will be available for any future drug candidates that we commercialize and, if available, what the level of reimbursement will be. The availability and extent of reimbursement may impact the demand for, or the price of, any future drug candidates for which we obtain regulatory approval. Payment rates may vary according to the use of the drug and the clinical setting in which it is used. If reimbursement is not available or is

available only to limited levels, we may not be able to successfully commercialize any future drug candidate that we successfully develop. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs and expenses invested in such drug, including research, development, manufacturing, marketing, distribution and sale.

Further, pursuant to a notice issued by seven PRC state agencies, including the NDRC and the NMPA, government price controls on pharmaceutical products were lifted effective as of June 1, 2015, except for narcotic drugs and first-class psychotropic drugs. As a result, prices of pharmaceutical products are currently determined mainly by market competition through the centralized tender process at the provincial level, without being subject to price ceilings set by the NDRC. However, for a pharmaceutical product to be included on the NRDL, a ceiling of such product's reimbursable amount under the national medical insurance will be determined, based on negotiation with the government. Moreover, there is no assurance that such market-based pricing mechanism will result in higher product pricing compared to government-controlled pricing, as competition from other manufacturers, particularly those offering the same products at more competitive prices may force us to lower price of our Boyounuo® (BA1101) and may also impact the prices of our drug candidates once commercialized in China. Any changes in price control policies, which we may not be able to predict or control, could create uncertainties affecting our product prices, revenue and profitability.

PRC government authorities have implemented policies that aim to further increase the affordability of pharmaceutical products. In an opinion issued in January 2021, the General Office of the State Council further encouraged the collective procurement of public hospitals through the centralized purchase of drugs in large quantities. A centralized tender process will be initiated once the demand for certain drugs reach a certain quantity or amount, with the emphasis on those high-priced drugs included on the NRDL in great demand. This policy is intended to reduce the retail prices of pharmaceutical products by cutting the intermediaries between hospitals and manufacturers. Consolidated procurement and direct settlement between hospitals and manufacturers may increase the bargaining power of hospitals and increase the pricing pressure on our future drug candidates. If PRC government authorities implement other reform on the current tender process for pharmaceutical products or revise other policies affecting pharmaceutical prices, which result in downward adjustments to the retail prices of our future drug candidates, our wholesale prices, our revenue and profitability could be adversely affected.

As the PRC is the primary market for Boyounuo® (BA1101) and most of the future drug candidates that we expect to commercialize, the laws and regulations of the PRC with respect to insurance reimbursement caps, healthcare reform initiatives or pricing on pharmaceuticals are particularly important to us. See "Regulatory Overview — Other laws and regulations in relation to medical industry — Laws and regulations in relation to basic medical insurance" for further details. Such policies may limit the prices that hospitals, clinics and other medical practitioners can charge for our products, which in turn would limit the prices that we can charge them and adversely affect our profitability. We will need to monitor the pricing policies of hospitals and other affected market participants and adjust our own pricing policy where appropriate in order to balance the competitiveness of our products with our profitability. As the PRC healthcare system as a

whole has undergone continuous reform in recent years in respect of insurance coverage, access to medical products and services, and the role of the private sector in drug development, we cannot predict if or when the PRC government will change the retail price ceilings in the future, if additional pharmaceutical products may become subject to price controls and/or more stringent insurance reimbursement limits. Any negative developments in respect of the above could have a material adverse effect on our business, financial condition and results of operations.

The market opportunities for our drug candidates may be smaller than we anticipate, which could render some drug candidates ultimately unprofitable even if commercialized.

We estimate the incidence and prevalence of target patient populations for particular diseases based on various third-party sources, such as scientific literature, surveys of clinics, patient foundations or market research, as well as internally generated analyses, and we use such estimates in making decisions regarding our drug development strategy, including determining which candidates to focus our limited resources on in pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data. The total addressable market opportunity will depend on, among other things, acceptance of the drug by the medical community and patient access, drug pricing, reimbursement and the availability of alternative treatments. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or access.

Furthermore, new studies may change the estimated incidence or prevalence of diseases, and the number of addressable patients for our drug candidates in any case may turn out to be lower than expected. In such cases, even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and results of operations.

We have relatively limited experience in manufacturing our drug candidates on a large commercial scale, which is a highly exacting and complex process.

Our Yantai Site houses a number of production lines with a capacity of 1,700L for pilot production and 8,000L for commercial production and two formulation filling lines for both pilot and commercial production, consisting of (i) the vial filling formulation line with a designed production capacity of 2.5 million vials per annum, and (ii) the pre-filled product formulation line of 3.5 million pre-filled syringes per annum. However, as we just recently began commercial manufacturing of our first product, Boyounuo® (BA1101), we have limited experience in large-scale production of our drugs for commercial use. Moreover, the manufacture of biologics is a highly exacting and complex process, due in part to strict regulatory requirements. If problems arise in the course of producing a batch of product, that batch may need to be discarded, which would result in additional expenses and may also lead to product shortages. If problems are not discovered before the product reaches the market, recall and product liability costs may also be incurred.

In the course of production, we may also face various other challenges such as, but not limited to:

- longer than expected lead up times to commence or ramp up production;
- failure to obtain sufficient work orders to efficiently utilize the full manufacturing capacity of the site;
- supply shortages that prevent us from scaling up production;
- excess supplies that may expire and be written off; and
- low success rate of manufacturing products that meet regulatory requirements or our quality standards.

We cannot assure you that we will be able to resolve such issues in a cost-effective and timely manner.

In addition, the NMPA and other regulatory authorities require that our drug candidates and products be manufactured according to GMP standards, which we may not be able to achieve or maintain for factors beyond our control, in which case such regulators may issue a warning against us, withdraw approvals for drug candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, halting of production and distribution, refusal to permit the import or export of products or imposing civil and criminal penalties. Such regulators may also withdraw approvals if unexpected problems occur with our drug candidates, including adverse events of unanticipated severity or frequency and side effects, which may lead to revisions to the approved labeling to add additional safety information, imposition of additional clinical studies to evaluate safety risks and/or other restrictions.

Any negative developments in respect of the above could have a material adverse effect on our business, financial condition and results of operations.

We have relatively limited experience in marketing and sales of our products and the commercialization of new products may require additional resources.

We rely on our in-house marketing force and third parties to market and promote our products. For example, on May 26, 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, regarding the promotion rights to Boyounuo® (BA1101) for a term of five years, under which we had granted to AstraZeneca China certain exclusive promotion rights in various counties across 12 provinces and autonomous regions in China. See "Business — Commercialization, sales, marketing and distribution — Third-party promoters" for further details. As we have just commenced commercial sales of Boyounuo® (BA1101), we do not have a proven track record of successfully marketing or selling our products. We have limited experience in building a commercial team, conducting a comprehensive

market analysis, obtaining licenses and approvals, or managing distributors and sales force for our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risks, take longer and cost more than it would if we were a company with sufficient experience launching drug candidates.

The commercialization of new products requires additional resources. The success of our sales and marketing efforts depends on our ability to attract, motivate and retain qualified and professional employees in our sales and marketing team who have, among other things, sufficient experience in sales and marketing of drug products and extensive industry connections with distributors and hospitals, and are able to communicate effectively with medical professionals. Furthermore, since we expect to launch new products, we expect to hire more employees with relevant experience and knowledge to strengthen our marketing and sales workforce. However, due to the intense competition for experienced personnel, we may be unable to attract, motivate and retain a sufficient number of qualified sales and marketing employees to support our business development and expansion, and our sales revenue and results of operations may be negatively affected.

In addition, we plan to continue strengthening our cooperative relationship with hospitals, physicians and research institutions for enhancing our product awareness in the market. For example, we may perform regular visits in hospitals, collaborate with leading universities and research institutions, and cooperate with key opinion leaders to conduct post-launch clinical studies to promote the market acceptance of our products. However, such promotional activities may not be as effective as we expected, or may be impeded by unanticipated events, which may cause a decline of our sales revenue, and have a material adverse effect on our business, financial condition and results of operations.

We may not be able to successfully commercialize LY-CovMab, one of our Core Products, or BA-CovMab, which may negatively affect our business, results of operations and business prospects.

The commercialization of LY-CovMab and BA-CovMab, our innovative antiviral drug candidates for prevention and treatment of COVID-19, is impacted by a variety of factors beyond our control, including viral mutations, and we may not be able to successfully commercialize either of them.

We began developing LY-CovMab in February 2020 and are conducting Phase 2 clinical trial in China. Based on our preliminary clinical findings, LY-CovMab could be a SARS-CoV-2 neutralizing antibody candidate against SARS-CoV-2. However, since late 2020, multiple SARS-CoV-2 variants have emerged. According to *in vitro* virus neutralization activity data, LY-CovMab has a neutralizing effect on Alpha, Delta, Gamma, Lambda variants, and has a limited neutralization effect on Omicron variant. The SARS-CoV-2 B.1.1.529 (Omicron) variant contains 15 mutations of the receptor-binding domain (RBD) and might evade RBD-targeted neutralizing antibodies according to the article "Omicron escapes the majority of existing SARS-CoV-2 neutralizing antibodies" published in *Nature* authored by Cao, Y., Wang, J., Jian, F. et al in 2022. Our clinical trials involve a lengthy and expensive process with an uncertain outcome and may not show favourable outcomes due to reasons such as SARS-CoV-2 becoming capable of evading

neutralizing antibodies via mutation and conferring resistance to monoclonal antibody candidates including LY-CovMab, which may adversely impact the efficacy of LY-CovMab. See "— Risks relating to the development, clinical trials and regulatory approval of our drug candidates — Successful results in earlier studies in the clinical development process may not be predictive of future trial results" in this section for further details. As numerous unforeseen events could arise during future clinical trials, we cannot guarantee when we could complete the Phase 2 and Phase 3 clinical trial for LY-CovMab or when we could commence its commercialization. See "— Risks relating to the development, clinical trials and regulatory approval of our drug candidates — We may encounter various delays in the preclinical programs, clinical development and regulatory approval process, which may result in delays in, or suspension of, the commercialization of our drug candidates" in this section for further details.

Moreover, there is uncertainty on the growth of the COVID-19 drug market given that the pandemic is being contained and the virus has become less virulent, which may adversely impact our LY-CovMab and BA-CovMab. If the trend continues and any further strains become less virulent, we may be unable to enroll a sufficient number of subjects for our clinical trials or the estimated market for LY-CovMab and BA-CovMab may shrink or no longer exist. Furthermore, in light of the emergence of other COVID-19 therapeutics and/or late-stage candidates in China and overseas, some of which could be more effective to cope with new COVID-19 variants, the market demand of LY-CovMab and BA-CovMab may also decrease due to such competition. In addition, the pandemic may have been controlled before we realize any return on our investment in the research and development of our drug candidates. If we are not able to successfully commercialize LY-CovMab, one of our Core Products, or BA-CovMab, our business, results of operations and business prospects may be negatively affected.

If we fail to manage our distributors effectively, or fail to maintain, expand and optimize an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected.

During the Track Record Period, we primarily rely on our network of distributors to distribute our products. We had an extensive distribution network of 160 distributors as of June 30, 2022, penetrating selected regions and reaching more than 1,100 target hospitals and institutions in China. Our ability to maintain and grow our business will depend on our ability to maintain, expand and optimize effective distribution channels that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributors, who may fail to distribute our products in the manner we contemplate, which may impair the effectiveness of our distribution network. Our distributors may take one or more of the following actions, any of which could have a material adverse effect on our business, prospects and reputation:

- underperforming or failing in their obligations to market and sell our products;

- breaching our agreements with them, including by selling products that have expired, or by selling products outside their designated territories or to hospitals other than their designated hospitals or engaging sub-distributors without our consent;

- failing to maintain the requisite licenses or otherwise failing to comply with applicable regulatory requirements when selling our products;
- violating anti-corruption, anti-bribery, competition or other relevant laws and regulations;
- failing to pay us for successful sales on a timely basis;
- choosing to distribute competing products, whether or not in violation of any exclusivity arrangements;
- negotiating lower pricing or less favorable payment terms;
- refusing to renew partnerships or terms on a commercially favorable basis or at all;
- refusing to work with us due to exclusivity arrangements with other companies;
- losing their capabilities in certain geographic regions, which could reduce the scope of our marketing and distribution network; and
- purchasing our products based on their own estimates and forecasts, which we cannot control and may have limited visibility on, and may materially reduce their orders without any notice to us.

Any violation or alleged violation by distributors of our distribution agreements or any applicable laws and regulations could result in the erosion of our goodwill, expose us to liabilities, disrupt our distribution network and create an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects. Since we do not require our distributors to sell our products on an exclusive basis, our products may also compete with similar products from our competitors sold by our distributors.

We typically enter into one-year agreements with our distributors. Our distributors might elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons. For example, if price controls or other factors substantially reduce the margins they can obtain through the resale of our products to hospitals, they may terminate their agreements with us. For about eight months ended December 31, 2021 since we commercialized Boyounuo® (BA1101) in 2021 and for the six months ended June 30, 2022, the aggregate sales to our five largest distributors were RMB129.9 million and RMB172.8 million, respectively, representing 81.8% and 78.3% of our revenue for the same period. Sales to our largest distributor for the same period were RMB48.3 million and RMB90.0 million, respectively, representing 30.4% and 40.8% of our revenue for the same period. If any of our major distributors, or a significant number of our distributors, voluntarily or involuntarily suspend or terminate their relationships with us, or we are otherwise unable to maintain and expand our distribution network

effectively, our sales volumes and business prospects could be adversely affected. If we fail to maintain our relationship with our distributor in any territory, in particular, an overseas market, our sales and performance in such territory would be adversely affected, if we may not be able to enter into new distribution relationships with other distributors in a timely manner, or at all. Many factors can affect our ability to establish or maintain such relationships, including that we may fail to find an appropriate partner for a desired overseas market, the costs of doing so are prohibitively high or legal or administrative procedures are overly complex and time consuming.

Consequently, any disruption to our distribution network, including our failure to maintain relationships, form new relationships or renew our existing distribution agreements could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, results of operations, financial condition and prospects. Additionally, in the event that a significant number of our distributors cease or reduce their purchases of our products or fail to meet the terms in our distribution agreements, our business, financial condition and results of operations may be materially and adversely affected.

Moreover, we adopt the single-layer distribution model with distributors who directly on-sell our products to hospitals and pharmacies and require our distributors to get the consent from us when they need to carry out secondary distribution. As of the Latest Practicable Date, we were not aware of any sub-distributors being engaged to distribute our products. We will not engage with any sub-distributors directly or maintain contractual relationships with them, and mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors and our policies and measures that our distributors agree to comply with. As a result, we will have limited control over these sub-distributors. To the best of our Directors' knowledge, we are currently in compliance with the Two-Invoice System, but there is no assurance that our distributors will not engage sub-distributors without obtaining our prior approval, resulting in violation of the Two-Invoice System, or any sub-distributor fails to comply with our distribution agreements and policies. For further details on the Two-Invoice System, see "Regulatory Overview — Other laws and regulations in relation to medical industry — Drug distribution and two-invoice system". Furthermore, we cannot assure you that we will be able to identify or correct all the sub-distributors' practices that are detrimental to our business in a timely manner or at all, which may adversely affect our results of operations and reputation. As there is no contractual relationship between us and these sub-distributors, we will have no direct legal recourse against them if their activities cause harm to our business or reputation. For further details on our distributors, see "Business — Commercialization, sales, marketing and distribution — Distributors".

We are exposed to credit risks relating to our trade and notes receivables and if we experience delays in collecting payments from our distributors, our cash flows and operations could be adversely affected.

We generally grant our distributors credit terms of one to three months, depending on the specific payment terms in each contract. As of December 31, 2020 and 2021 and June 30, 2022, our trade receivables were nil, RMB78.1 million and RMB109.8 million,

respectively. As of December 31, 2020 and 2021 and June 30, 2022, our loss allowance amounted to nil, nil and RMB26,000, respectively. For details on the impairment analysis of our trade and notes receivables, see note 17 to the Accountants' Report in Appendix I in this document. The average trade receivables turnover days were 59.0 days and 76.6 days, respectively, in 2021 and for the six months ended June 30, 2022. For our sales to distributors, our distributors receive payments from hospitals for our products they sold to them, which could be used for payments to us. If our distributors' cash flows, working capital, financial condition or results of operations deteriorate or they experience delays in payments from the hospitals, they may be unable, or they may otherwise be unwilling, to make payments owed to us promptly or at all. Any substantial defaults or delays in distributor's payment to us could materially and adversely affect our cash flows, and we could be required to terminate our relationships with distributors in a manner that will impair the effective distribution of our products.

Credit risk for trade and notes receivables arises when our distributors default on their contractual obligations which may result in financial losses. We perform the impairment analysis periodically using a provision matrix to measure expected credit losses. Although we seek to maintain strict control over our outstanding receivables and have a credit control department to minimize credit risk, we cannot assure you that we are or will be able to accurately assess the creditworthiness of each of our distributors before entering into agreements or extending credit terms, nor can we guarantee that each of these distributors will be able to strictly follow and enforce the payment schedules provided in the agreements. Any inability of our distributors to pay us in a timely manner may adversely affect our liquidity and cash flows, which in turn has a material adverse effect on our business operations and financial condition.

We may provide for impairment losses for prepayments, other receivables and other assets.

Our prepayments mainly represent our purchase of raw materials used and related expenses for research and development activities as well as raw materials used for pilot and commercial production and our other receivables mainly represent Phase 3 clinical trial costs of BA9101 to be received from OcuMension. As of December 31, 2020 and 2021 and June 30, 2022, our prepayment, other receivables and other assets were RMB68.1 million, RMB75.3 million and RMB68.1 million, respectively. As of December 31, 2020 and 2021 and June 30, 2022, our loss allowance was assessed to be minimal. For details on the impairment analysis of our prepayment, other receivables and other assets, see note 18 to the Accountants' Report in Appendix I in this document. However, subject to the future business operations and market conditions, we may provide for impairment losses for our prepayments, other receivables and other assets. Should this occur, our results of operations and financial conditions may be adversely affected.

RISKS RELATING TO INTELLECTUAL PROPERTY

We may be subject to intellectual property infringement or misappropriation claims or other legal challenges, which could cause us to incur significant expenses, pay substantial damages and delay or prevent us from selling our products or using technologies incorporated in our drug candidates or future drugs.

Our success depends, in part, upon our technologies, drug candidates and operations not infringing, misappropriating or violating intellectual property rights owned by others and being able to resolve claims of intellectual property infringement and/or misappropriation expeditiously without major financial expenditures or adverse consequences. Many pharmaceutical companies, including the ones that developed the reference drugs for which we are developing biosimilars, have developed worldwide patent portfolios of varying sizes and breadth. Many patents may cover a marketed product, including but not limited to, the composition of the product, methods of use, formulations, cell line constructions, vectors, growth media, production processes and purification processes. Not all such patents have expired globally, including potentially in the jurisdictions where we are developing and intend to commercialize our biosimilar drug candidates. Sponsors of the reference drugs may submit applications for patent term extensions in jurisdictions where extensions are available seeking to extend certain patent protection on a reference drug, which, if approved, may interfere with or delay the launch of one or more of our biosimilar products. Comparatively, innovative biological drugs such as one of our Core Products, LY-CovMab, face relatively higher uncertainty of patent infringement because, unlike biosimilars, they may not rely on expiration of patents relating to reference drugs to assess potential infringement risks. Furthermore, it is possible that we might fail to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our innovative drug candidates or their contemplated therapeutic uses. A new therapeutic area in its preliminary development stage, such as the treatment of COVID-19 that our LY-CovMab focuses on, is very dynamic and it makes the patent or patent application search more challenging. In addition, the exact scope of patent claims if and when issued may differ from its scope in the application stage, and as a result, we cannot ensure that our drug candidates will not infringe patents that are issued in the future. Based on the freedom to operate ("**FTO**") analysis of our Core Products, we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize Core Products in China at the contemplated timeframe. Based on the FTO analysis of BA1102 and BA6101, we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize BA1102 and BA6101 in the United States and the EU at the contemplated timeframe. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to determine whether any existing patents cover a company's products, and whether making, using, offering to sell, or selling the products would infringe any existing patents. The potential scope of an FTO investigation can be immense and all patent databases used in such investigations have limitations. Patent applications in China, the United States and other jurisdictions are typically not published until 18 months after the original filing, or in some cases, may not be published until patent issuance. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our drug candidates may infringe, or which such third parties claim to be

infringed by our technologies. Therefore, we cannot guarantee that our FTO searches and analysis have exhaustively reviewed all the existing and future patents that potentially cover our products. Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our drug candidates, technologies or methods.

As the pharmaceutical biologics industry expands and more patents are issued, and as we expand our portfolio accordingly, we may be exposed to greater risk of claims of infringement of patent rights. Given the nature of the biologics industry, we may, in the ordinary course of business, be subject to intellectual property infringement or misappropriation claims in various jurisdictions where we operate and where our drugs are ultimately sold. Patent and trademark infringement, trade secret misappropriation and other intellectual property claims and proceedings brought against us, whether successful or not, can be complex and time-consuming and could result in substantial costs, negative publicity and harm to our reputation and market position. Such claims and proceedings can also distract and divert our management and key personnel from other tasks important to the success of our business. Moreover, the legal threshold for initiating such claims and proceedings is low, so that even claims with a low probability of success could be initiated and require significant resources and attention to defend. We could also be subject to intellectual property claims related to alleged infringements by our third party partners, such as suppliers. Intellectual property litigation or disputes could force us to do one or more of the following:

- cease developing, manufacturing or selling products that incorporate the challenged intellectual property;
- cease the use and registration of certain names, domain names, brands or trademarks in connection with some or all of our products and business activities in some or all jurisdictions throughout the world;
- obtain and pay for licenses from the holder of the infringed intellectual property right, which licenses may not be available on reasonable terms, or at all;
- redesign or reengineer products;
- change our business processes; and
- pay substantial damages, court costs and attorneys' fees, including potentially increased damages for any infringement or violation found to be willful.

Any intellectual property-related disputes or litigation, regardless of outcome or merit, could result in substantial costs and expenses, adverse publicity or diversion of management resources, any of which could have a material adverse effect on our business, financial condition and results of operations.

A portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents, and if our pending patent applications fail to receive approval, our business will be adversely affected. If we are unable to obtain, maintain and adequately protect our intellectual property rights, our business could suffer.

Our business relies on, and will continue to rely on, various intellectual property rights, including patents, trademarks, trade secrets, copyright and designs to protect our product and research findings, brand name, reputation, product appearance and technology. We have sought to protect our proprietary position by filing patent applications in China, United States, Europe, Australia, Canada, Japan, Brazil and other jurisdictions related to novel technologies and drug candidates that we consider are important to our business. As of the Latest Practicable Date, we had 25 granted patents and 44 pending patent applications worldwide. See "Business — Intellectual property" for further details of our intellectual property. However, the patent and other intellectual property position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual considerations, and is subject to frequent litigation. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications are typically not published until at least several months after filing, or in some cases not at all. Industry players cannot be certain that they were the first to make the inventions claimed in their patents or pending patent applications, or that they were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of any intellectual property rights is highly uncertain. Moreover, changes in either the patent laws or interpretation of the patent laws in various countries where our applications or patents are filed may diminish the value of our patents or narrow the scope of our patent protection.

Effective intellectual property protection is expensive to develop and maintain, and the costs of defending and maintaining our rights may also be significant. To the extent that we become involved in patent disputes, any adverse determination against us could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. As we intend to sell our successfully commercialized drugs in various jurisdictions including China, United States, Europe and elsewhere, we are dependent on the laws of a wide range of jurisdictions to protect, maintain and enforce our intellectual property rights throughout the world. We have not yet sought intellectual property protection in all jurisdictions where we ultimately intend to sell our products, and as a result of commercial pressures or otherwise, we may significantly expand our business into such jurisdictions without the benefit of clear, enforceable intellectual property protections. The laws of these jurisdictions may also be insufficient to protect our intellectual property rights to the same extent or in the same manner as the laws of the jurisdictions in which we currently have sought intellectual property protections or of the jurisdictions where investors may be located.

Many companies have encountered significant problems in protecting, obtaining and defending intellectual property rights in certain jurisdictions. In particular, the legal systems of certain developing countries do not favor or consistently enforce patents, trade secrets, trademarks and other forms of intellectual property protection, which could make it difficult and time-consuming to stop the infringement, misappropriation or other violation of our intellectual property rights. Competitors may be able to use our proprietary technology and other intellectual property rights in jurisdictions where intellectual property protection may not be prioritized by the relevant legal systems. Furthermore, we cannot assure you as to the degree and scope of protection which our existing or future patents may afford us over our drug candidate portfolio. For example, there is no assurance that any of our pending patent applications will finally lead to issued patents. Likewise, we cannot assure you that:

- competitors will not develop similar or superior products outside the protection of our patents;
- competitors will not infringe on our patents;
- we will have adequate resources to enforce our patents; or
- we will obtain sufficient remedies in the case of infringement, misappropriation, or other violations of our patents.

We cannot assure you that we will be able to file, prosecute, transfer and maintain all necessary or desirable intellectual property applications at a reasonable cost or in a timely manner, or that we will always be able to identify patentable aspects of our research and development output before it is too late to obtain patent protection, nor can we provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future. If we are unable to obtain and maintain patent in respect of any of our current and future patent applications and other intellectual property protection for our products, drug candidates and other technologies, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We depend on patents, trademarks, trade secrets and other forms of intellectual property protections, but these protections may not be adequate.

We rely on a combination of patent, trademark, trade secret and other intellectual property laws in China, the United States and elsewhere to protect our intellectual property. However, these protections may not prove meaningful against competitive offerings or otherwise be commercially valuable. For example, even if we do obtain issued patents that purport to provide adequate protection for our products, the issuance of a patent is not conclusive as to its ownership, scope, validity or enforceability and, as such, our patents may be challenged in courts and patent offices throughout the world. We may not be successful in bringing or defending such patent infringement challenges. Such challenges may result in our patents being narrowed in scope, invalidated or held

unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drug candidates, or limit the duration for the patent protection of our technology and drug candidate. As a result of actual or threatened patent infringement claims, we could also be prevented from entering into licenses on commercially acceptable terms or at all. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, inter parties review, derivation or post-grant proceedings regarding intellectual property rights with respect to our current or future products. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights. This could have a material adverse effect on our business, financial condition and results of operations. Moreover, successful patents may not issue in a form that will provide us with any meaningful protection against competitors who may be able to circumvent our patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

In addition, we cannot assure you that we will be successful in obtaining additional intellectual property or enforcing our intellectual property rights against unauthorized users. We also rely on unregistered proprietary rights, including know-how and trade secrets related to development, manufacturing and distribution of biosimilars and other product candidates. Confidentiality agreements entered into between us and our employees and other third parties prohibiting them from disclosing proprietary information or technology may not provide meaningful protection for us, and may not effectively prevent leakage or unauthorized disclosure of trade secrets and other proprietary information. In addition, intellectual property enforcement may be unavailable in some countries. Furthermore, third parties who are not party to our confidentiality agreements may obtain access to our trade secrets or know-how, and others may independently develop similar or equivalent trade secrets or know-how. The disclosure or use of our intellectual properties or technologies by others, including our competitors, could reduce or eliminate any competitive advantage we have developed, cause us to lose sales opportunities or otherwise harm our competitive position, which could have a material adverse effect on our business, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annual fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (中華人民共和國國家知識產權局) ("**CNIPA**"), the United States Patent and Trademark Office ("**USPTO**") and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a

number of procedural, documentary, and other similar provisions during the patent application process. We rely on our outside counsel to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The illegal and/or parallel imports and counterfeit biopharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates.

In addition, counterfeit pharmaceutical products are not expected to meet our or our rigorous manufacturing and testing standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our brand name(s). In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

RISKS RELATING TO OUR OPERATIONS

Our business and operations could be adversely affected by the effects of health pandemics or epidemics, including the outbreak of COVID-19, in regions where we, or third parties on which we rely, have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 outbreak. See "Business — Impact of COVID-19 outbreak" for further details of the impact of COVID-19 on us. Countries across the world, including both China and the United States, have imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. In addition, our employees could be subject to quarantine policies implemented by local authorities to combat COVID-19. These policies and restrictions may negatively impact our manufacturing capability, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These disruptions in our operations could negatively impact our business, operating results and financial condition. If one or more similar, or more severe, outbreaks were to occur, they could negatively impact our business, operating results and financial condition.

In addition to our employees, restrictions related to COVID-19 or other infectious diseases could impact the availability or cost of raw materials. See "— Risks relating to our operations — Failure to maintain optimal inventory levels could increase our inventory holding costs or cause us to lose sales" in this section for further details.

Furthermore, our clinical trials could be affected by the COVID-19 or other outbreaks. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward an outbreak and some patients may not be able to comply with clinical trial protocols if quarantines or other restrictions impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients as well as principal investigators and site staff who, as healthcare providers, may have heightened exposure to disease, could be delayed or disrupted, which would adversely impact our clinical trial operations.

The economic fallout of the COVID-19 outbreak, or other outbreaks that cause a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it has already resulted in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could negatively affect our liquidity in the future. In addition, a recession or market correction resulting from an outbreak, including the spread of COVID-19, could materially affect our business and the value of our Shares.

We operate in a competitive industry and may fail to compete effectively.

The biologics market is highly competitive, characterized by extensive research and development, technological change, frequent modifications and enhancements, innovations, new applications, evolving industry standards and changes in consumer behavior and preferences. We expect this high level of competition to increase over time as our industry continues to develop. Our ability to remain competitive depends in large part upon our ability to innovate, develop and market new products and technologies that meet the needs of treatment providers in a timely manner.

We face competition across several bases, including, but not limited to, treatment indication, drug novelty, drug quality and reputation, prevalence of adverse side effects, breadth of our portfolio, manufacturing and distribution capacity, ability to protect intellectual property or other confidential information, research and development pipeline, drug price, coverage and depth of customer and supplier relationships. We compete against both domestic and international companies in the biologics space. As we continue to invest in discovering and developing a broader and more complex portfolio, we may face competition in new therapeutic areas, and competitors in that space may be significantly further along in the development of such therapeutics. Moreover, we expect increased competition as additional companies enter our market and as more advanced technologies become available. Some of our competitors may have greater financial, research and other resources, greater pricing flexibility, more extensive technical capabilities, greater sales and marketing efforts, longer track record of successfully commercializing new drugs and greater name recognition. These may include foreign competitors whose products have already received approval overseas and are seeking to obtain approval in the PRC. Since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018, data from overseas clinical trials can be accepted for BLA and our competitors can file an application for drug marketing authorization in China by submitting relevant overseas research materials in accordance with the requirements of the application materials. It is likely that our foreign competitor candidates will ultimately be approved and commercialized overseas before our candidates. For example, as of the Latest Practicable Date, there were 11 clinical-stage Prolia® (denosumab) biosimilar candidates globally (outside of China), including our BA6101. See "Industry Overview — Competitive landscape" for further details on competition faced by our Core Products. Such competitors, if approved and commercialized overseas, may be able to leverage existing approvals to obtain PRC approval more quickly than domestic developers, and may also be able to leverage international brand recognition to capture market share. Furthermore, our competitors may improve the quality of their products, introduce new products at lower cost and with

improved efficacy or safety characteristics, or adapt more quickly to new or emerging technologies and changes in demand and requirements. If we are unable to timely and regularly introduce new drugs and enhancements on an ongoing basis, our drugs, even if successfully commercialized, may become obsolete over time and lose market share.

If we do not successfully introduce new competitive drugs in a timely manner, or if our competitors develop products with the same indication as ours before we are able to do so, or if prices of reference drugs to which our biosimilar drug candidates relate decrease, we could face significant pricing pressure on our drugs or find it commercially unfeasible to even bring such drugs to market, which in turn would result in us being unable to generate our target profits for such drugs, if at all, and render us unable to recover our investment. Biologics companies may be able to secure a first-entrant advantage in the market. Immediately following commercial launch, first-entrants can also obtain post-marketing clinical data from end-customers before competitors that can help confirm the biosimilar product's benefits, effectiveness and safety, which further elevates the barrier of entry for second-movers. As a result of such first-entrant advantages, if other biosimilars of such products are approved and successfully commercialized before our drug candidates of the same originator products, we may not be able to achieve significant market share for these products.

We cannot assure you that we will be able to compete effectively with existing competitors or maintain our competitive position over time. Any of the above developments could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face challenges associated with operating on a geographically dispersed basis, making it difficult to evaluate our current business and predict our future performance.

We are headquartered in China with R&D teams in China and United States and business teams in China and Singapore. Operating on a geographically dispersed basis with operations in multiple regions presents unique coordination, geographic, political and other challenges. These include, for example:

- Travel restrictions related to the COVID-19 pandemic have limited the ability of our senior management to freely travel between China and other relevant locations;

- Our clinical studies in humans are conducted in China, the United States, Europe and various Asia Pacific countries or regions, which requires we effectively manage, among other things, numerous clinical trials and regulatory regimes and our CROs and other collaborators who assist us in our various drug development activities;

- Trade, regulatory and political tensions between China, the United States and other jurisdictions may limit our ability to timely and effectively: conduct drug development activities (including conducting clinical trials and obtaining necessary regulatory approvals); secure needed manufacturing capacity and timely and effective delivery of clinical and commercial drug supplies where needed; commercialize our drug candidates; secure desired license rights for new drug candidates; and secure collaboration partners for our internally developed drug candidates; and

- We are exposed to a number of other risks that could adversely affect our business and financial results including: unexpected changes in laws and regulatory requirements in local jurisdictions; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain jurisdictions; enforcement of anti-corruption and anti-bribery laws, such as the United States Foreign Corrupt Practices Act of 1977, as amended; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable local tax regimes and potentially adverse tax consequences; and significant adverse changes in local currency exchange rates.

In light of the rapidly evolving and highly competitive biotechnology industry, it is difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential investors to lose all or substantially all of their investment in our business.

Failure to retain the services of our senior management and key scientific personnel could severely disrupt our business and growth.

Our success significantly depends upon the continued service of our senior management and key scientific personnel. If we lose any of our senior management and key scientific personnel, including Ms. Jiang and Dr. Dou, we may not be able to identify, hire and train suitable qualified replacements and may incur additional expenses and time to recruit and train new personnel, which could severely disrupt our business and growth. In addition, although each member of our senior management and key scientific personnel has signed a non-compete agreement with us, we may not always be able to successfully enforce these provisions should any of them leave us. Any of the above developments could severely disrupt our business and growth.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.

The global biologics market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2020 and 2021, our research and development costs amounted to RMB236.3 million and RMB231.6 million, respectively, and for the six months ended June 30, 2021 and 2022, they amounted to RMB111.6 million and RMB169.1 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our services. We intend to continue to enhance our technical capabilities in drug discovery, development, and manufacturing, which are capital and time intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may render our technologies obsolete, which could significantly reduce demand for our services and harm our business and prospects.

Our success depends on our ability to attract, train, motivate and retain highly skilled scientists and other technical personnel.

Our success depends on our team of scientists and other technical personnel and their ability to keep pace with cutting-edge technologies and developments in biologics. In particular, scientists with education, training and experience at renowned research universities and pharmaceutical or biotechnology companies are in particularly high demand both in China and globally. As a result, such scientists are well-sought after by our competitors and we may face challenges in attracting and retaining skilled scientists and other technical personnel. We compete vigorously with pharmaceutical and biotechnology companies, other biologics outsourcing services providers and research and not be able to hire and retain enough skilled and experienced scientists or other technical personnel at the current level of wages. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with changes in customer needs and technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition and results of operations.

Our current manufacturing facilities expose us to geographic concentration risk.

We rely on our Yantai Site for a substantial part of our product manufacturing needs. As a result, we are exposed to a risk of supply disruption if production at Yantai, China is interrupted. In addition, substantially all of our inventory of drug substance and drug products are stored in the same area. As a result, contaminations, power failures, the

breakdown or substandard performance of equipment, the destruction of equipment and other property due to natural disasters (including but not limited to flooding, typhoons, earthquakes and mudslides), acts of terror or other third party interference (in each case, whether affecting our site directly or the Yantai geographical area generally) could severely impact our ability to maintain quality inventories or receive adequate and timely supplies. Moreover, while our manufacturing facilities are not within the vicinity of any other facilities handling dangerous goods and chemicals, we utilize various hazardous chemicals in the ordinary course of our R&D, quality control testing and workspace maintenance activities at our facilities. While we generally maintain only limited amounts of these hazardous chemicals and enforce thorough precautionary measures, we cannot assure you that we will be able to, at all times, prevent dangerous incidents such as fires or explosions. If there is such an unexpected interruption in the supply of our products or damage to our inventory or facilities, we may be unable to manufacture sufficient products and satisfy customer orders on a timely basis, if at all. As a result, we could suffer loss of market share which may not be recaptured and incur other penalties, and our reputation could be harmed, which could materially and adversely affect our business, financial condition and results of operations.

We may not be able to effectively manage our anticipated growth or execute our growth strategies.

Our growth strategies include, among other things, accelerating clinical development of our pipeline products towards commercialization overseas, enriching our innovative portfolio and strengthening our marketing capability and accelerate the commercialization of our drug candidates. See "Business — Our strategies" for further details of our strategies. Pursuing such strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global biologics market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased marketing and customer support activities, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute our growth strategies or realize our anticipated growth could adversely affect our business, financial condition and results of operations.

We may not realize the benefits of collaborations which we have entered into or may enter into in the future.

We have entered into agreements with AstraZeneca China and OcuMension, among others, and to pursue several collaborations. We carefully select our partners and products in order to collaborate and align interests and leverage each other's capabilities and infrastructure to develop significant products and bring novel therapies to patients in an efficient and cost-effective manner. We also plan to explore collaboration with reputable international partners to expand overseas presence. See "Business — Our strategies" for further details of our strategies.

At this time, we cannot predict what form such strategic collaborations might take in the future. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates, because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with additional third parties for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to such third parties. Further, collaborations involving our drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates;

- a collaborator with marketing and distribution rights to one or more of our drug candidates may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates.

As a result, we may not be able to realize the benefit of or choose to exercise any options under current or future collaborations or strategic partnerships, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay our R&D program or one or more of our other R&D programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We may not be able to maintain effective quality control over our products.

The quality of our products depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. See "Business — Manufacturing — Quality management systems" for further details. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardize any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

Any failure to comply with existing regulations and industry standards or any adverse actions by the drug approval authorities against us could negatively impact us.

In many jurisdictions where we intend to commercialize our products, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop and manufacture such drug. For example, we may need to obtain clearance from the NMPA, FDA, EMA or other relevant regulatory authorities in the event that pre-clinical studies are filed as part of an IND application to seek authorization to begin clinical trials, or clinical trials are filed as part of a NDA, biologic license application or other filing to seek marketing approval. These regulatory authorities may conduct scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. We cannot assure you that we will be able to pass all inspections and obtain or maintain all necessary clearance in relation to biologics discovery, development and manufacturing from the regulatory authorities.

In addition, the biologics industry in China as well as other jurisdictions we intend to expand into in the future are highly regulated and constantly evolving, with laws, regulations and policies that are subject to change. If we fail to comply or keep abreast with laws and regulations, industry standards and policies, we could be subject to fines or other punitive actions against us. In addition, our ongoing biologics development projects could be terminated and any data we submitted to regulatory authorities could be disqualified, each of which could have a material adverse impact on our reputation, business, financial condition and results of operations and prospects. In addition, any action against us for violation of the relevant regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Our failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect us.

We are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including the relevant regulatory authorities ordering us to cease operations, implement potentially costly corrective measures or any other action which could materially disrupt our business operations.

In addition, some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. We cannot assure you that we will be able to successfully procure such renewals and/or reassessment when due, and any failure to do so could severely disrupt our business.

Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect requiring us to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, we cannot assure you that we will successfully obtain them, which in turn could restrict our scope of permitted business activities and constrain our drug development and revenue generation capability.

Any of the above developments could have a material adverse effect on our business, financial condition and results of operations.

We depend on a stable and adequate supply of quality materials, including reagents and consumables and R&D and manufacturing equipment, from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

Our business operations require raw materials, such as reagents, culture media and other materials needed for research and development purposes. For the years ended December 31, 2020 and 2021, the raw materials and consumables component of our total research and development costs amounted to RMB92.7 million and RMB54.5 million, respectively, and for the six months ended June 30, 2021 and 2022, they amounted to

RMB24.4 million and RMB41.1 million, respectively. In the event of significant price increases for such materials for reasons such as decreasing supply, interruption of transportation or otherwise, we cannot assure you that we will be able to raise the prices of our products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability.

In addition, any significant disruption in our supplier relationships could harm our business. For example, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs would increase significantly once we enter commercial production of drugs once they receive marketing approval. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to keep up with our growth needs or may reduce or cease their supply of materials to us at any time. In addition, we cannot assure you that our suppliers have obtained and will be able to renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations, and failure to do so by them may lead to interruption in their business operation, which in turn may result in shortage of materials supplied to us. Any interruption in our supply of materials due to any of the above or for any other reason would force us to procure supplies from replacement suppliers, which may not be available to us on commercially favorable terms or at all. This in turn could have a material adverse effect on our business, financial condition and results of operations.

We are exposed to product liability and other liability risks.

Given the nature of our business in developing biologics to treat complex diseases, we are exposed to inherent risks of being subject to product liability claims alleging that our drugs, whether used in clinical trials or commercially, have resulted in or could result in an unsafe condition or injury to patients. We may also be exposed to other liability lawsuits, such as other tort or regulatory claims. Such lawsuits could be costly to defend and could result in significant damages in excess of any applicable insurance caps, reduced sales, significant liabilities and diversion of management's time, attention and resources. Even claims without merit could subject us to adverse publicity, harm our reputation among customers and require us to incur significant legal fees to defend. Consequently, product liability claims and lawsuits, regardless of their ultimate outcome, could have a material adverse effect on our business, financial condition and results of operations.

We are subject to the risks of doing business globally. Specifically, we may explore the licensing of commercialization rights or seek collaborations worldwide, which will expose us to additional risks of conducting business in additional international markets.

We have R&D teams in China and United States, and business teams in China and Singapore. We conduct our clinical trials in China, United States, Europe and other jurisdictions and may in the future operate in other jurisdictions. As a result, our business is subject to risks associated with doing business globally. In addition, global markets are

an important component of our growth strategy. Outside China, we intend to focus on opportunities in the United States and the European Union, in particular. If we fail to obtain or grant licenses or enter into collaboration arrangements with third parties in these markets, or if an existing or future third-party collaboration is not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;

- unexpected changes in laws and regulatory requirements and difficulty of effective enforcement of contractual provisions in local jurisdictions;

- inadequate intellectual property protection such as third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;

- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;

- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;

- economic weakness, including inflation;

- compliance with tax, employment, immigration and labor laws for employees traveling abroad;

- the effects of applicable foreign tax structures and potentially adverse tax consequences;

- currency fluctuations, which could result in increased operating expenses and reduced revenue;

- workforce uncertainty and labor unrest;

- failure of our employees and contracted third parties to comply with anti-corruption and anti-bribery laws, such as United States Department of the Treasury's Office of Foreign Assets Control rules and regulations and the United States Foreign Corrupt Practices Act of 1977, as amended; and

- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics (including, for example, the outbreak of COVID-19).

These and other risks may materially adversely affect our ability to procure equipment and raw material and to attain or sustain any future revenue from international markets.

Increased labor costs could slow our growth and affect our profitability.

Our operations require a sufficient number of qualified employees. In recent years, the average labor cost in the pharmaceutical market has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further increase in labor cost. If there is a significant increase in our labor cost, our operations and profitability may be adversely affected.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.

We maintain insurance coverage which we believe to be in line with the industry norm in the jurisdictions where we operate, such as product liability insurance for our Commercialized Product and insurance related to clinical trials for our Core Products. We also plan to procure product liability insurance to address any potential product liability claims from third parties after the commercialization of our product candidates, e.g., BA1102, BA6101 and BA9101. However, our insurance coverage may be insufficient to cover any such claims relating to the above or such claims may be excluded from insurance coverage, which in turn may result in us incurring substantial costs and a diversion of resources, and the occurrence of such incidents may lead to an increase in our insurance premiums.

We are subject to environmental protection, health and safety laws and regulations, and may be exposed to potential costs for compliance and liabilities, including consequences of accidental contamination, biological hazards or personal injuries.

Our business operations are subject to national and local laws and regulations pertaining to environmental protection and health and safety, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in our biologics discovery, development and manufacturing process. Due to the nature of biologics development and manufacturing activities, we cannot fully eliminate the risk of accidental contamination or exposure to biological hazards in the course of our operations. In the event of any such accidents, we could be held liable for damages, clean-up costs, and administrative actions against us, in addition to suffering potentially significant disruptions to our manufacturing capability (see "— Our current manufacturing facilities expose us to geographic concentration risk" for further details). In addition, both our existing and planned manufacturing facilities can only begin

operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved such facilities. Our safety production expenses were RMB0.1 million, RMB0.5 million and RMB0.9 million in 2020, 2021 and for the six months ended June 30, 2022, respectively, the majority of which was incurred for environmental law compliance purpose.

As the requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may have difficulties complying with, or accurately predicting the potentially substantial cost of complying with, these laws and regulations, which may subject us to rectification orders, substantial fines, monetary damages and suspension or cessation of research activities and other business operations. Any of the above negative developments could have a material and adverse impact on our business, financial condition and results of operations and prospects.

Our reputation is key to our business success. Negative news or publicity about us, any of our Controlling Shareholders or any member of them, Directors or our management may adversely affect our reputation, business and growth prospects.

Any negative news or publicity concerning us, our Controlling Shareholder, Directors, management, affiliates or any entity that shares the Boan Biotech or Luye brand name, even if proven untrue, could adversely affect our reputation, business and growth prospects. We cannot assure you that negative publicity about us or any of our affiliates or any entity that shares such names would not damage our brand image. Given our specialized industry and market, negative publicity and word of mouth could travel quickly and negatively impact our relationships with third parties, which could have a material adverse effect on our business, financial condition and results of operations.

We may be involved in litigation, legal disputes, claims or administrative proceedings which could be costly and time-consuming to resolve.

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. Any litigation or proceeding to which we become a party might result in substantial costs and divert management's attention and resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as changes in the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Our insurance might not cover claims brought against us, provide sufficient payments to financially cover all of the costs to resolve such claims or continue to be available on terms acceptable to us.

Failure to comply with anti-corruption laws could subject us to investigations, sanctions or fines, which may harm our reputation and materially and adversely affect us.

We have adopted policies and procedures designed to ensure that we and our researchers, marketing and sales personnel and other staff comply with anti-bribery and anti-corruption laws in the course of sales and marketing, drug research and development. See "Business — Internal controls and risk management" for further details.

However, the healthcare sector in China generally poses elevated risks of violations of anti-bribery and anti-corruption laws, particularly in the context of improper payments to facilitate improved outcomes in research studies or drug supply negotiations, as well as securing sales opportunities at hospitals and other medical institutions. The PRC government has implemented various anti-bribery and anti-corruption regulations to address and mitigate such practices, including requiring market participants to adopt internal controls and risk management measures addressing bribery and corruption risks and undergo periodic inspections from relevant regulatory authorities as to their anti-bribery and corruption status. We cannot assure you that our researchers, marketing and sales personnel and other staff, as well as third parties that we collaborate with, such as business partners, CROs, PIs, hospitals and medical professionals, will fully comply with anti-bribery and anti-corruption regulations at all times, or that we or they will be able to detect and identify all instances of improper practices in respect of our clinical trials and other parts of our business. In the event of any bribery or corruption incidents involving our employees or parties otherwise associated with us, we may be subject to investigations, sanctions or fines, and our reputation could be significantly harmed by any negative publicity stemming from such incidents, which may materially and adversely affect our business, financial condition, results of operations and prospects.

Our risk management and internal control systems, as well as the risk management tools available to us, may not fully protect us against various risks inherent in our business.

We have established risk management and internal control systems consisting of relevant organizational frameworks, policies, procedures and risk management methods in order to manage our risk exposure, primarily including market risk, credit risk, liquidity risk, operational risk, compliance risk and legal risk, and we expect to continue to improve such risk management and internal control systems from time to time. See "Business — Internal controls and risk management" for further details of our risk management. However, our risk management and internal control systems may not be fully effective in mitigating our risk exposure in all market environments or against all types of risks, including risks that are unidentified or unanticipated.

In addition, we will become a [**REDACTED**] company upon completion of this [**REDACTED**], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. In addition, in preparation for this [**REDACTED**], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

Our risk management capabilities are limited by the information, tools or technologies available to us. If our internal control system fails to detect potential risks in our business as intended, or is otherwise exposed to weaknesses and deficiencies, our business, financial condition and results of operations could be materially and adversely affected.

Effective implementation of our risk management and internal controls policies and procedures also depends on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that affect our business with sufficient time to plan for contingencies for such events, our business, financial condition and results of operations could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

If our products and supplies are not stored and shipped properly, the products and supplies could be damaged, which could negatively affect us.

Our biologics and related supplies may become unusable or unsafe for use when exposed to unfavorable environmental conditions or when stored or shipped improperly. If we or any applicable third party fails to provide and maintain proper storage and shipping for our research and development supplies and ingredients, our products or drug candidates, such products could become unsuited for further use and require replacement orders, which could be costly and delay our operating activities and in turn, have a material adverse effect on our business, financial condition and results of operations.

Failure to maintain optimal inventory levels could increase our inventory holding costs or cause us to lose sales.

As of December 31, 2020 and 2021 and June 30, 2022, the carrying amount of our inventories was RMB19.7 million, RMB98.8 million and RMB140.9 million, respectively, accounting for approximately 21.4%, 10.5% and 18.5%, respectively, of our total current assets as of the same day. The average turnover days of our inventories and finished goods in 2021 were 408.7 days and 111.7 days, respectively, as a result of the sales of Boyounuo® (BA1101) that commenced in May 2021. The average turnover days of our inventories and our finished goods for the six months ended June 30, 2022 decreased to 293.8 days and 57.1 days, respectively, mainly due to the increased sales of Boyounuo® (BA1101). Our ability to maintain optimal inventory levels is impacted by a variety of factors beyond our control, including restrictions related to COVID-19 or other infectious diseases, changing reimbursement policies and launches of competing products. For stocking purposes, we generally estimate demand for the products we sell ahead of the actual time of sale. We cannot assure you that we can accurately predict these trends and events and maintain adequate levels of inventory at all times. While many of our raw materials including reagents, culture media and other materials needed for research, development and manufacturing purposes may be obtained from more than one supplier, there is a risk that port closures and other restrictions resulting from the COVID-19 outbreak in the region

may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug candidates. Such inventory under-stock may cause us to lose sales and our business, financial condition, results of operations and prospects may also be materially and adversely affected.

On the other hand, we may be exposed to increased inventory risks due to the accumulation of excess inventory of our products or raw materials as a result of reasons such as slow-moving inventory as well as the restrictions and lockdowns related to COVID-19. An unexpected decrease in the market demand for the products we sell could lead to excessive or obsolescent inventory, and we may be forced to offer discounts to dispose of slow-moving inventory, which in turn may materially and adversely affect our financial condition and results of operations.

If we are found to have violated laws protecting the confidentiality of patients and other covered information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business.

We may be subject to patient privacy regulation by governments in the jurisdictions in which we conduct our business or clinical trials. There are numerous laws in the jurisdictions in which we operate that protect the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. Local and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities and potentially result in regulatory penalties and significant legal liability, if our information security efforts fail. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, The Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》), which became effective in June 2017, created China's first national-level data protection for "network operators" referring to the owners or administrators of a network as well as network service providers. The Data Privacy Law of the PRC (《中華人民共和國數據安全法》), which took effect in September 2021, provides for a security review procedure for the data activities that may affect national security. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (the "**Personal Information Protection Law**"), which became effective from November 2021, provides the circumstances under which a personal information processor could process personal information and the requirements for such circumstances. The Personal Information Protection Law clarifies the scope of application, the definition of personal information and sensitive personal information, the legal basis of personal information processing and the basic requirements of notice and consent.

Determining whether protected information has been handled in compliance with applicable privacy and other standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Any mishandling, access, breach or loss of information could result in legal claims or proceedings, reputational harm and liability under the laws that protect information, which could have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

The regulations of the People's Republic of China on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019 and implemented on July 1, 2019 stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources, or HGR, at clinical institutions without export of HGR materials. However, the two parties shall file the type, quantity and usage of the HGR to be used with the administrative department of science and technology under the State Council before clinical trials. These regulations are important to our business because all transfers of patient starting material from hospitals to labs must be reported to the relevant administrative departments under these provisions. While we currently are in full compliance with these provisions, it is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux. Many statutory requirements include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

The Cybersecurity Review Measures (《網絡安全審查辦法》) became effective on February 15, 2022, which stipulates that the operators carrying out data processing activities that affect or may affect national security, shall conduct cyber security review. According to the Cybersecurity Review Measures, an operator who controls more than one million users' personal information must report to the cyber security review office for a cyber security review if it intends to be listed abroad. In addition, on November 14, 2021, the Cyberspace Administration of China (the "**CAC**") publicly solicited opinions on the Draft Data Security Regulations (《網絡數據安全管理條例(徵求意見稿)》), which requires data processors to comply with certain requirements during their daily operation and further stipulates that data processors shall apply for cyber security reviews in certain situations including any data processor intending to be listed in Hong Kong that affects or may affect national security. However, neither the Cybersecurity Review Measures nor the Draft Data Security Regulations provides any further explanation or interpretation for "listed abroad" or "affects or may affect national security." As of the Latest Practicable Date, the Draft Data Security Regulations has not been formally adopted. We cannot guarantee whether we will be subject to the cyber security review for our future capital raising activities or if new rules or regulations promulgated in the future will impose additional compliance requirements on us. Compliance with these and any other applicable laws, regulations, standards and obligations relating to data privacy, security and transfers is a rigorous and time-intensive process and may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, fines, penalties, judgments, negative publicity and reputational damage, and may otherwise materially and adversely affect our business, financial condition and results of operations. We may not be able to respond quickly or effectively to regulatory, legislative and other developments, and these changes may in turn impair our ability to offer our existing or planned drug candidates or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We depend on information technology and other infrastructure that are exposed to certain risks, including cyber security risks.

We rely on a variety of information technology and automated operating systems to manage or support our operations, including protecting our intellectual property. The proper functioning of these systems is critical to the efficient operation and management of our business. In addition, these systems may require modifications or upgrades as a result of technological changes or growth in our business. These changes may be costly and disruptive to our operations and could impose substantial demands on management time. Our systems and those of third-party providers may be vulnerable to damage or

disruption caused by circumstances beyond our control, such as catastrophic events, power outages, natural disasters, computer system or network failures, viruses or malware, physical or electronic break-ins, unauthorized access, cyber-attacks and thefts. We cannot assure you that the measures and steps we take to secure our systems and electronic information are adequate. Any significant disruption to our systems could result in unauthorized disclosure of confidential information and adversely affect our business and operating results.

We do not fully comply with relevant PRC laws and regulations in connection with contribution to social insurance and housing provident funds for some of our employees and we may be subject to penalties.

During the Track Record Period, some of our PRC subsidiaries engaged third-party human resources agencies to pay on our behalf social insurance premium and housing provident funds for 35 of our total 631 employees as of June 30, 2022, mainly because such employees work in a number of cities where we do not have legal entities to pay social insurance premium or housing provident funds for them locally. Such arrangements, although not uncommon in China, are not in strict compliance with relevant PRC laws and regulations. Pursuant to the PRC laws and regulations, we are required to pay social insurance premium and housing provident funds for our employees under our own accounts instead of making payments under third-party accounts. The contributions to social insurance premium and housing provident funds made through third-party accounts may not be viewed as contributions made by us, and as a result, we may be required by competent authorities to pay the outstanding amount, and could be subject to late payment penalties or enforcement application made to the court.

Our Directors believe that such non-compliance would not have a material adverse effect on our business and results of operations, considering that: (i) considering the facts stated above, paying social insurance premium or housing provident funds through third-party agencies does not harm the benefits of employees, and will not result in any material adverse effect on our business operation or this [**REDACTED**]; (ii) the total amount involved is insignificant and such non-compliance will not have any material adverse effect on our financial condition or results of operations taken as a whole; (iii) the 35 employees are fully aware of, and undertake in writing, among others, not to challenge or dispute the arrangements, (iv) our Controlling Shareholder, Shandong Luye, undertakes in writing to fully compensate us for all losses suffered from any administrative penalties in connection with such non-compliance occurred before [**REDACTED**], such as fees or pecuniary penalties; (v) none of the third-party human resources agencies has failed to pay, or delayed in paying, any social insurance premiums or housing provident fund contributions for our employees, (vi) to our knowledge and based on the confirmations issued by the competent government authorities, we had not been subject to any administrative penalties in relation to the agency arrangements during the Track Record Period; (vii) as of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for any amount in addition to what we have paid to the social insurance and housing provident funds either directly or through third-party human resources agencies; and (viii) we were neither aware of any employee complaints filed against us nor involved in any labor disputes with our employees with respect to the payment of social insurance or housing provident funds through third party agencies during the Track Record Period and up to the Latest Practicable Date.

However, we cannot assure you that the relevant competent government authority will not be of the view that this third-party agency arrangement does not satisfy the requirements under the relevant PRC laws and regulations, nor can we assure you that such authority will not impose fees, pecuniary penalties or other administrative actions on us for our noncompliance. Furthermore, if the human resource agencies fail to pay the social insurance premium or housing provident fund contributions, we may be ordered to rectify such failure or be subject to penalties, and our financial condition and results of operations may be adversely affected.

We may face penalties for the non-registration of our lease agreements in China.

As of the Latest Practicable Date, only one of our lease agreements for properties leased in the PRC had completed lease registration with relevant regulatory authorities. Non-registration of lease agreements does not affect the validity of such lease agreements. However, pursuant to the requirements of the Administrative Measures for Commodity House Leasing and relevant local rules, the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000 for each of these leasing properties. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our cost, in the future.

RISKS RELATING TO DOING BUSINESS IN THE PRC

We are subject to political, economic and social developments as well as the laws, rules, regulations and licensing requirements in the PRC, and any disruptions in these respects may materially affect us.

Most of our businesses, assets and operations are located in or derived from our activities in the PRC, and as a result, our business, financial condition and results of operations are subject, to a significant degree, to the economic, political, social and regulatory environment in the PRC. We are unable to accurately predict the precise nature of all the risks and uncertainties that we face and many of these risks are beyond our control.

The economy of the PRC differs from the economies of most developed countries in many respects, including, among others, the extent of government involvement, level of development, growth rate, and control of foreign exchange and allocation of resources. The PRC economy has been undergoing a transition from a planned economy to a market-oriented economy. The PRC government has, in recent years, implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, however a substantial portion of productive assets in the PRC is still owned by the PRC government. In addition, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government still retains significant control over the PRC's

economic growth through the allocation of resources, controlling payment of foreign currency denominated liabilities, setting monetary policy and providing preferential treatment to particular industries or enterprises.

Our performance will continue to be affected by the PRC economy, which in turn is influenced by the global economy. The PRC GDP decreased in the first quarter and gradually recovered since the second quarter of 2020. The impact of COVID-19 on the PRC economy is likely to be continuous and severe. Any prolonged slowdown in the Chinese economy may materially and adversely affect our business and results of operations. Moreover, trade wars among major economies may affect the availability and cost of various imported goods, including potentially equipment and materials which we rely on in our operations. Most notably, the United States government has made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of the EU, imposing tariffs against the United States in response. These trade wars may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive for us to procure from overseas suppliers or even becoming illegal to export. Accordingly, our ability to maintain and utilize our R&D facility in Boston may be adversely affected as we may not be able to procure the equipment and materials necessary for such facility or transfer data or materials from such facility out of the United States or into China in a timely manner or at all. In addition, trade tension among the countries may also lead to changes in laws and policy, which could make it more costly, difficult or time-consuming for us to obtain regulatory approval for our drug candidates in the United States. Similarly, our patent applications that are currently pending in the United States could also be negatively impacted by escalations in the trade wars.

Any of the above factors may materially and adversely affect our business, financial condition and results of operations.

Uncertainties with respect to the PRC legal system could have a material adverse effect on us.

Our business and operations are conducted in the PRC and governed principally by the PRC laws and regulations. The PRC legal system is based on written statutes, and prior court decisions can only be cited as reference. Since 1979, the PRC government has promulgated laws and regulations in relation to economic matters such as foreign investment, corporate organization and governance, commerce, taxation, finance, foreign exchange and trade, with a view to developing a comprehensive system of commercial law. However, China has not developed a fully integrated legal system and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China, or may be unclear or inconsistent.

In particular, since the PRC biologics industry is experiencing ongoing development and reform, the laws and regulations relating to this industry are sometimes unspecific and may be incomprehensive. Recent regulatory initiatives in China include (i) the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) released by the CFDA in November 2015, which clarified

and optimized the review and approval regime for clinical trial applications and accelerated the approval of drugs in urgent clinical need, (ii) Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) promulgated in October 2017 by the General Offices of the CPC Central Committee and the State Council, which seeks to streamline the clinical trial process and shorten the time line, and provide special fast-track approval for new drugs and devices in urgent clinical need and drugs and devices for rare diseases, (iii) the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) (the "**2017 Opinions**") promulgated by the CFDA in December 2017, which further clarified that a fast track clinical trial approval or drug registration pathway will be available to innovative drugs and (iv) the Circular on Issues Concerning Optimising Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly promulgated by the CFDA and National Health Commission in May 2018, which further simplified and accelerated the clinical trial approval process. In order to ensure the reform measures have legal ground, the Standing Committee of the NPC issued the Drug Administrative Law of the PRC (Revised in 2019) (《中華人民共和國藥品管理法(2019修訂)》) (the "**Revised Drug Administration Law**") on August 26, 2019 to solicit public comments. According to the Revised Drug Administration Law, the major changes include the following: (i) improvement of the whole-process supervision system of drugs; (ii) clarification and improvement of regulatory responsibilities and measures for drugs by requiring drug regulatory authorities to inspect the implementation of GMP by marketing authorization holders as well as production and operation processes, establishing a new system for the appointment of professional drug inspectors and maintenance and publicly disclosing drug safety credit records; (iii) significantly increase the penalties for violations; (iv) official implementation of the marketing authorization holder system; (v) reform of the drug approval system; (vi) cancelation of the GMP certifications for drugs and GSP for pharmaceutical products; and (vii) replacement of approval by registration of clinical trial organizations and improvement of the approval procedure for clinical trials, etc. Certain changes under the Revised Drug Administration Law include canceling the requirement that drug manufacturers obtain GMP certification, while introducing the requirement that companies establish a quality management system to ensure ongoing compliance of manufacturing processes, and also be subject to supervision and inspection of drug regulatory authorities for their ongoing compliance with relevant requirements. The transition from certification to ongoing compliance imposes higher and stricter requirements for the GMP practices of companies. For the purpose of coordinating the implementation of the Revised Drug Administration Law, the NMPA published an announcement on Issuing Three Documents Including the Word Procedures for the Evaluation of Breakthrough Therapy Drugs (for Trial Implementation) (《關於發布〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》) in July 2020, which abolishes the 2017 Opinions and stipulates the evaluation procedures for breakthrough therapy drugs, drugs conditionally approved and priority review.

However, there remains a limited volume of published decisions, often of a non-binding nature, and the interpretation and enforcement of PRC laws and regulations involve uncertainties and can be inconsistent, and such difficulties may be exacerbated by contradictory provincial or local regulations. Moreover, PRC laws and regulations relating to the biologics industry could further intensify and add to the burden of

interpretation and compliance for companies operating in the changing environment. Even where adequate laws exist in China, the enforcement of existing laws or contracts based on existing laws may be uncertain or sporadic, and it may be difficult to obtain swift and equitable enforcement of judgments or arbitral awards. Our Articles of Association provide that disputes or claims of rights between holders of H Shares and our Company, our directors, supervisors, managing directors or other senior management or holders of Domestic Shares arising out of any rights or obligations concerning our affairs conferred or imposed thereupon by our Articles of Association or the PRC Company Law and other relevant laws and administrative regulations are to be resolved through arbitration. Our Articles of Association further provide that any arbitral award will be final, conclusive and binding on all parties. A claimant may elect to submit a dispute to an arbitration organization in Hong Kong or the PRC. Awards that are made by PRC arbitral authorities recognized under the Arbitration Ordinance of Hong Kong can be enforced in Hong Kong. Hong Kong arbitration awards may be recognized and enforced by PRC courts, subject to the satisfaction of certain PRC legal requirements.

In addition, the PRC legal system is based in part on government policies and internal rules (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until sometime after the violation. In addition, any litigation in China may be protracted and result in substantial costs and the diversion of resources and management's attention. We cannot predict future developments in the PRC legal system or the effects of such developments, and the materialization of all or any of these uncertainties could have a material adverse effect on our financial position and results of operations.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management.

Most of our Directors and officers reside within the PRC, and most of our assets and their respective assets are located within the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon us or most of our Directors and officers, including with respect to matters arising under the U.S. federal securities laws or applicable state securities laws. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in the PRC or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement

in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a Chinese court is expressly designated as the court having sole jurisdiction for the dispute. On January 18, 2019, the Supreme People's Court and the Hong Kong SAR Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the "**New Arrangement**"), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the Mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People's Court and the completion of the relevant legislative procedures in the Hong Kong SAR. The New Arrangement will, upon its effectiveness, supersedes the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. Moreover, we cannot assure you that all final judgments that are compliant with the Arrangement will be recognized and effectively enforced by a PRC court.

The discontinuation of any of the financial incentives currently available to us in China could adversely affect us.

We have historically benefited from government grants as incentives for our research and development activities. We had government grants of RMB10.9 million and RMB4.3 million in our consolidated statements of profit or loss and other comprehensive income for the years ended December 31, 2020 and 2021, and they amounted to RMB1.3 million and RMB6.9 million for the six months ended June 30, 2021 and 2022, respectively. We also recorded government grant of RMB2.8 million, RMB1.8 million and nil as of December 31, 2020 and 2021 and June 30, 2022, respectively, in our consolidated statements of financial position. Moreover, we also enjoy preferential tax treatment with respect to certain of our operations such as manufacturing and R&D in China, though as a loss-making company we did not incur any tax expenses during the Track Record Period. Our eligibility to receive these financial incentives requires that we continue to qualify for them. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine at any time to eliminate or reduce these financial incentives, generally with prospective effect. Since our receipt of the financial incentives is subject to periodic time lags and inconsistent government practice, as long as we continue to receive these financial incentives, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these financial incentives in addition to any business or operational factors that we may otherwise experience. The discontinuation of financial incentives currently available to us could have a material adverse effect on our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

In March 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the "**Scientific Data Measures**"), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to any foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Fluctuation in the value of the Renminbi may have a material adverse effect on our business.

We conduct most of all our business in Renminbi, which is our reporting currency. However, following the [**REDACTED**], we may also maintain a significant portion of the [**REDACTED**] from the [**REDACTED**] in Hong Kong dollars before they are used in our PRC operations. The value of the Renminbi against the US dollar, Hong Kong dollar and other currencies may be affected by changes in the PRC's policies and international economic and political developments. As a result of these and any future changes in currency policy, the exchange rate may become volatile, the Renminbi may be revalued further against the US dollar or other currencies or the Renminbi may be permitted to enter into a full or limited free float, which may result in an appreciation or depreciation in the value of the Renminbi against the US dollar or other currencies. For the years ended December 31, 2020 and 2021, we had exchange losses of nil and RMB5.9 million, respectively. For the six months ended June 30, 2022, we had exchange gain of RMB2.6 million. Fluctuations in exchange rates may adversely affect the value, translated or converted into US dollars or Hong Kong dollars (which are pegged to the US dollar), of our cash flows, revenues, earnings and financial position. For example, an appreciation of the Renminbi against the US dollar or the Hong Kong dollar would make any new Renminbi-denominated investments or expenditures more costly to us, to the extent that we need to convert US dollars or Hong Kong dollars into Renminbi for such purposes.

Governmental control of currency conversion may adversely affect the value of your investment, and payment of dividends is subject to restrictions under PRC law and regulations.

The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of foreign currency out of the PRC. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends, or otherwise satisfy foreign currency denominated obligations.

Under existing PRC foreign exchange regulations, payments of current account items, including the payment of dividends, interest payments and expenditures from the transaction, can be made in foreign currencies without prior approval from the SAFE by complying with certain procedural requirements. However, approval from appropriate governmental authorities is required where Renminbi is to be converted into foreign currency and remitted out of the PRC to pay capital expenses such as the repayment of bank loans denominated in foreign currencies. Further, the PRC government may also restrict access to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our currency demands, we may not be able to pay certain of our expenses as they come due or to pay dividends in foreign currencies.

Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Non-PRC resident individual holders of H Shares whose names appear on the register of members of H Shares of our Company ("**non-PRC resident individual holders**") are subject to PRC individual income tax on dividends received from us. The tax on dividends must be withheld at source. Pursuant to the Circular on Questions Concerning the Collection of Individual Income Tax following the Repeal of Guo Shui Fa [1993] No. 045 (《關於國税發[1993]045號文件廢止後有關個人所得税徵管問題的通知》) (Guo Shui Han [2011] No. 348) dated June 28, 2011 issued by the SAT, the tax rate applicable to dividends paid to non-PRC resident individual holders of H Shares varies from 5% to 20% (usually 10%), depending on whether there is any applicable tax treaty between the PRC and the jurisdiction in which the non-PRC resident individual holder of H Shares resides. Non-PRC resident individual holders who reside in jurisdictions that have not entered into tax treaties with the PRC are subject to a 20% withholding tax on dividends received from us. See "Taxation and Foreign Exchange — The PRC taxation" in Appendix III to this document for further details. In addition, under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得税法》) and its implementation regulations, non-PRC resident individual holders of H Shares are subject to individual income tax at a rate of 20% on gains realized upon sale or other disposition of H Shares. However, pursuant to the Circular Declaring That Individual Income Tax Continues to Be Exempted over Income of Individuals from Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得税的通知》) issued by the MOF and the SAT on March 30, 1998, gains of individuals derived from the transfer of listed shares in enterprises may be exempt from individual income

tax. To our knowledge, as of the Latest Practicable Date, in practice the PRC tax authorities had not sought to collect individual income tax on such gains. If such tax is collected in the future, the value of such individual holders' investments in H Shares may be materially and adversely affected.

Under the EIT Law and its implementation regulations, a non-PRC resident enterprise is generally subject to enterprise income tax at a rate of 10% with respect to its PRC-sourced income, including dividends received from a PRC company and gains derived from the disposition of equity interests in a PRC company, subject to reductions under any special arrangement or applicable treaty between the PRC and the jurisdiction in which the non-PRC resident enterprise resides. Pursuant to a Notice promulgated by the SAT on November 6, 2008, we intend to withhold tax at 10% from dividends payable to non-PRC resident enterprise holders of H Shares (including [**REDACTED**]). Non-PRC enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities' approval. There are uncertainties as to the interpretation and implementation of the EIT Law and its implementation rules by the PRC tax authorities, including whether and how enterprise income tax on gains derived upon sale or other disposition of H Shares will be collected from non-PRC resident enterprise holders of H Shares. If such tax is collected in the future, the value of such non-PRC enterprise holders' investments in H Shares may be materially and adversely affected.

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares.

Prior to the [**REDACTED**], there was no [**REDACTED**] market for our H Shares. The initial [**REDACTED**] for our H Shares to the [**REDACTED**] was the result of negotiations between us and the [**REDACTED**] (for itself and on behalf of the [**REDACTED**]), and the [**REDACTED**] may differ significantly from the market price for our H Shares following the [**REDACTED**]. We have applied for [**REDACTED**] of, and permission to deal in, our H Shares on the Stock Exchange. A [**REDACTED**] on the Stock Exchange, however, does not guarantee that an active trading market for our H Shares will develop, or if it does develop, will be sustained following the [**REDACTED**] or that the market price of our H Shares will not decline following the [**REDACTED**].

The trading volume and market price of our H Shares may be volatile, which may result in substantial losses for investors subscribing for or purchasing our H Shares pursuant to the [REDACTED].

The price and trading volume of our H Shares may be highly volatile as a result of various factors. Some of these factors are beyond our control, including:

- actual or anticipated fluctuations in our results of operations (including variations arising from foreign exchange rate fluctuations);
- news regarding recruitment or loss of key personnel by us or our competitors;

- announcements of competitive developments, acquisitions or strategic alliances in our industry;
- changes in earnings estimates or recommendations by financial analysts;
- potential litigation or regulatory investigations;
- changes in general economic conditions or other developments affecting us or our industry;
- changes in any relevant government policies or regulations;
- price movements on international stock markets, the operating and stock price performance of other companies, other industries and other events or factors beyond our control; and
- release of lock-up or other transfer restrictions on our outstanding Shares or sales or perceived sales of additional Shares by the Controlling Shareholder or other Shareholders.

Future sales or perceived sales or conversion of substantial amounts of our Shares in the public market, including any future offering of H Shares or conversion of our [REDACTED] Shares into H Shares, could have a material adverse effect on the prevailing market price of our H Shares and our ability to raise additional capital in the future, or may result in dilution of your shareholding.

The market price of our H Shares could decline as a result of future sales or issuances of a substantial number of our H Shares or other securities relating to our H Shares in the public market, or the perception that such sales or issuances may occur. Moreover, such future sales or perceived sales may also adversely affect the prevailing market price of our H Shares and our ability to raise capital in the future at a favorable time and price. The H Shares held by the Controlling Shareholder are subject to certain lock-up undertakings for a period of up to twelve months after the [**REDACTED**]. See "[**REDACTED**]" for further details. We cannot assure you that they will not dispose of their Shares they may own now or in the future.

Immediately upon the completion of the [**REDACTED**], we will have two classes of ordinary shares, H Shares and Domestic Shares. All of our Domestic Shares are [**REDACTED**] Shares which are not [**REDACTED**] or traded on any stock exchange. According to the stipulations by the State Council's securities regulatory authority and the Articles of Association, our [**REDACTED**] Shares may be converted into H Shares, and such converted H Shares may be [**REDACTED**] or traded on an overseas stock exchange provided that prior to the conversion and trading of such converted H Shares, the requisite internal approval processes (but without the necessity of Shareholders' approval by class) have been duly completed and the approval from the relevant PRC regulatory authorities, including the CSRC, have been obtained. In addition, such conversion, trading and [**REDACTED**] shall in all respects comply with the regulations prescribed by

the State Council's securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange.

Furthermore, if additional funds are raised through our issuance of new equity or equity-linked securities other than on a pro-rata basis to existing Shareholders, the percentage ownership for such Shareholders may be reduced. Such new securities may also confer rights and privileges that take priority over those conferred by the H Shares.

You will incur immediate and significant dilution and may face further dilution if we issue additional Shares in the future.

The [**REDACTED**] for our H Shares is higher than the net tangible assets book value per H Share initially issued to our Shareholders prior to the [**REDACTED**]. Consequently, purchasers of our H Shares in the [**REDACTED**] will face an immediate dilution in the pro forma combined net tangible assets book value of RMB3.95 (HK$4.89) per H Share based on the maximum [**REDACTED**] of HK$[**REDACTED**], and our Shareholders prior to the [**REDACTED**] will experience an increase in the pro forma combined net tangible assets book value per H Share of their H Shares. Moreover, we may in the future consider seeking a [**REDACTED**] of our Shares in jurisdictions other than Hong Kong, which would similarly dilute the holdings of our H Share investors.

The market price of our H Shares when trading begins could be lower than the [REDACTED], since there will be a gap of several days between [REDACTED] and [REDACTED] of our H Shares.

The [**REDACTED**] will be determined on the [**REDACTED**]. However, the [**REDACTED**] will not commence trading on the Stock Exchange until they are delivered, which is expected to be on the fifth Business Day after the [**REDACTED**]. As a result, there will be a gap of several days between [**REDACTED**] and [**REDACTED**] of our H Shares and investors may not be able to sell or otherwise deal in the [**REDACTED**] during that period. Accordingly, holders of the [**REDACTED**] are subject to the risk that the price of the [**REDACTED**] when trading begins could be lower than the [**REDACTED**] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

We cannot assure you that the H Shares will remain [REDACTED] on the Stock Exchange.

Although it is currently intended that the H Shares will remain [**REDACTED**] on the Stock Exchange, there is no guarantee of the continued [**REDACTED**] of the H Shares. Among other factors, our Company may not continue to satisfy the [**REDACTED**] requirements of the Stock Exchange. Holders of H Shares would not be able to sell their H Shares through trading on the Stock Exchange if the H Shares were no longer [**REDACTED**] on the Stock Exchange.

Our Controlling Shareholders have substantial control over our Company and their interests may not be aligned with the interests of the other Shareholders.

Prior to and immediately following the completion of the [**REDACTED**], our Controlling Shareholders will remain having substantial control over our Company. Subject to the Articles of Association, the Companies Ordinance and the PRC Company Law, the Controlling Shareholders will be able to exercise significant control and exert significant influence over our business or otherwise on matters of significance to us and other Shareholders by voting at the general meeting of the Shareholders and at Board meetings. The interest of the Controlling Shareholders may differ from the interests of other Shareholders and they are free to exercise their votes according to their interests. To the extent that the interests of the Controlling Shareholders conflict with the interests of other Shareholders, the interests of other Shareholders can be disadvantaged and harmed.

We have significant discretion as to how we will use the [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the [**REDACTED**] from the [**REDACTED**] in ways you may not agree with or that do not yield a favorable return to our shareholders. We plan to use the net [**REDACTED**] from the [**REDACTED**] to, among other things, invest in drug R&D projects, expand our commercialization resources and capability and supplement working capital. See "Future Plans and [**REDACTED**]" for further details. However, our management will have discretion as to the actual application of our [**REDACTED**]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the [**REDACTED**] from this [**REDACTED**].

Certain facts and other statistics with respect to the biologics industry and market in this document may not be fully reliable.

Certain facts and other statistics in this document relating to the biologics industry and market have been derived from various sources and publicly available data. However, we cannot guarantee the quality or reliability of these sources. They have not been prepared or independently verified by us or any of the [**REDACTED**] and, therefore, we make no representation as to the accuracy of such facts and statistics. Due to possibly flawed or ineffective collection methods or discrepancies between published information and market practice and other problems, the facts and statistics herein may be inaccurate or may not be comparable to facts and statistics produced for other economies. As a result, prospective investors should consider carefully how much weight or importance they should attach to or place on such facts or statistics. Investors should read the entire document carefully and should not consider any particular statements in published media reports without carefully considering the risks and other information contained in this document.

There may be coverage in the media or other publications regarding the [REDACTED] and our operations, and we strongly caution you not to place any reliance on any information contained therein.

We do not accept any responsibility for the accuracy or completeness of the information and make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media or other publications and we strongly caution you not to place any reliance on any information contained therein. To the extent that any of the information in the media is inconsistent or conflicts with the information contained in this document, we disclaim it. Accordingly, prospective investors should read the entire document carefully and should not rely on any of the information in press articles or other media or research analyst coverage. Prospective investors should only rely on the information contained in this document and the [**REDACTED**] to make investment decisions about us.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains certain statements and information that are forward-looking and uses forward-looking terminology such as "believe," "expect," "estimate," "predict," "aim,""intend," "will," "may," "plan," "consider," "anticipate," "seek," "should," "could," "would," "continue," and other similar expressions. You are cautioned that reliance on any forward-looking statement involves risks and uncertainties and that any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect. In light of these and other risks and uncertainties, the inclusion of forward-looking statements in this document should not be regarded as representations or warranties by us that our plans and objectives will be achieved and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events, or otherwise. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

We may not declare dividends on our H Shares in the future.

The amount of dividends actually distributed to our Shareholders will depend upon our earnings and financial position, operating requirements, capital requirements and any other conditions that our Directors may deem relevant and will be subject to the approval of our Shareholders. There is no assurance that dividends of any amount will be declared or distributed in any year.

WAIVERS FROM STRICT COMPLIANCE WITH THE REQUIREMENTS UNDER THE LISTING RULES AND EXEMPTION FROM THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In preparation for the [**REDACTED**], our Group has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemption from strict compliance with the relevant provisions of Companies (Winding Up and Miscellaneous Provisions) Ordinances:

MANAGEMENT PRESENCE

Pursuant to Rule 8.12 and Rule 19A.15 of the Listing Rules, an issuer must have sufficient management presence in Hong Kong and, in normal circumstances, at least two of the issuer's executive directors must be ordinarily resident in Hong Kong.

Our Company has only two executive Directors who are not, and for the foreseeable future will not be, ordinarily resident in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules. Our Group's business operations and assets are primarily based outside Hong Kong, and it would be practically difficult and not commercially necessary for us to relocate our executive Director to Hong Kong for the purpose of satisfying the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules, or to appoint additional executive Directors solely for the purpose of satisfying Rule 8.12 and Rule 19A.15 of the Listing Rules. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has] granted us, a waiver from compliance with Rule 8.12 and Rule 19A.15 of the Listing Rules on the basis that the following measures have been adopted by us:

(a) we have appointed Ms. Jiang Hua (姜華), our executive Director and chairlady of the Board, and Ms. Lai Siu Kuen (黎少娟) ("**Ms. Lai**"), our company secretary, pursuant to Rule 3.05 of the Listing Rules who will act as our Company's principal channel of communication with the Stock Exchange. Ms. Lai is ordinarily resident in Hong Kong. Each of our authorized representatives will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone, facsimile and email. Each of the two authorized representatives is authorized to communicate on our behalf with the Stock Exchange;

(b) both our authorized representatives have means to contact all members of our Board (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange wishes to contact the members of our Board for any matters. Our Directors who are not ordinarily resident in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with the Stock Exchange within a reasonable period of time, when required. All Directors have provided his/her mobile phone numbers, fax numbers and e-mail addresses (where available) to our authorized representatives. In the event that a Director expects to travel, he/she will endeavor to provide the phone number of the place of his/her accommodation to our authorized representatives or maintain an open line of communication via his/her mobile phone and all Directors and authorized

representatives have provided his/her mobile numbers, office phone numbers, fax numbers and email addresses (where available) to the Stock Exchange;

(c) we have appointed Maxa Capital Limited as our compliance adviser (the "**Compliance Adviser**") pursuant to Rule 3A.19 and Rule 19A.05 of the Listing Rules, which has access at all times to our authorized representatives, Directors, senior management and other officers of our Company, and will act as an additional channel of communication with the Stock Exchange in addition to the authorized representatives of our Company; and

(d) meetings between the Stock Exchange and our Directors could be arranged through our authorized representatives or the Compliance Adviser, or directly with our Directors within a reasonable time frame. We will promptly inform the Stock Exchange of any changes of our authorized representatives and/or the Compliance Adviser.

INDEPENDENT NON-EXECUTIVE DIRECTORS

Pursuant to Rule 19A.18(1) of the Listing Rules, an issuer incorporated in the PRC must have at least one of the independent non-executive directors ordinarily resident in Hong Kong.

All Directors are ordinarily resident in the PRC and our three independent non-executive Directors who are not, and for the period commencing from the [**REDACTED**] to the Company's forthcoming annual general meeting expected to be held in the first quarter of 2023 will not be, ordinarily resident in Hong Kong for the purpose of satisfying the requirements under Rule 19A.18(1) of the Listing Rules. Currently, all our Directors including the independent non-executive Directors reside in the PRC. Accordingly, we have applied to the Stock Exchange for, and Stock Exchange [has] granted, a waiver from strict compliance with Rule 19A.18(1) of the Listing Rules based on the following grounds:

(a) there are practical difficulties for our Company to appoint an additional independent non-executive Director who ordinarily resides in Hong Kong upon [**REDACTED**] based on the facts that:

(i) in light of the ongoing COVID-19 pandemic and the relevant social and travel restrictions, our Company, being a company principally operating in the PRC, requires a significant amount of time to find a suitable candidate ordinarily residing in Hong Kong to act as an additional independent non-executive Director and complete our internal approval and appointment process, including but not limited to convening a meeting for the Board;

(ii) according to the Articles of Association, our Company needs to convene an extraordinary general meeting for the appointment of a Director. Our Company needs to notify our Shareholders 15 days in advance before such general meeting;

(iii) according to our Articles of Association, our Company needs to have nine directors and independent non-executive Directors shall constitute no less than one-third of the Directors. As our Company currently has nine directors (including three independent non-executive Directors), appointment of an additional independent non-executive Director who is ordinarily resident in Hong Kong may result in amendment to the Articles of Association for which our Company needs to fulfill relevant procedures and the requirement of convening an extraordinary general meeting as described under sub-section (ii) immediately above; and

(iv) the candidate for the independent non-executive Director needs to comply with certain requirements before the nomination, such as attending a director's training in relation to directors' duties in Hong Kong, which will take a significant amount of additional time and will substantially delay the [**REDACTED**].

Accordingly, the appointment of an additional independent non-executive Director who ordinarily resides in Hong Kong upon [**REDACTED**] will incur significant additional time and costs and will substantially delay the [**REDACTED**], which would be unduly burdensome and prejudicial to the interest of our Company and Shareholders as a whole.

(b) Every Director has been appointed for a term of three years, subject to retirement by rotation at least once every three years. Accordingly, our Company undertakes that it will appoint a resident who ordinarily resides in Hong Kong as an independent non-executive Director at its forthcoming annual general meeting which is expected to be held in the first quarter of 2023 to fully comply with Rule 19A.18(1) of the Listing Rules.

(c) The waiver of strict compliance with Rule 19A.18(1) of the Listing Rules would not result in undue risks to the Shareholders and investors in our Company and would not repugnant to, or conflict with the duties of, the Stock Exchange under the SFO or the general principles under Rule 2.03 of the Listing Rules taking into accounting the following factors. During the period from the [**REDACTED**] to our Company's annual general meeting to be held in the first quarter of 2023, the Company will adopt the following

arrangements to ensure a communication channel between the Stock Exchange and our Directors (including the independent non-executive Directors):

(i) Ms. Lai, our company secretary and one of our authorized representatives, is ordinarily resident in Hong Kong and will act as our Company's principal channel with the Stock Exchange. Each of our authorized representatives including Ms. Lai has means to contact all members of our Board (including the independent non-executive Directors) promptly at all times as and when the Stock Exchange wishes to contact the members of our Board for any matters;

(ii) both our authorized representatives have means to contact all members of our Board (including the independent non-executive Directors) promptly at all time as and when the Stock Exchange wishes to contact members of our Board for any matters. Our Directors who are not ordinarily resident in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with the Stock Exchange within a reasonable period of time, when required. All Directors have provided his/her mobile phone numbers, fax numbers and e-mail addresses (where available) to our authorized representatives, in the event that a Director expects to travel, he/she will endeavor to provide the phone number of the place of his/her accommodation to our authorized representatives or maintain an open line of communication via his/her mobile phone and all Directors and authorized representatives have provided his/her mobile numbers, office phone numbers, fax numbers and email addresses (where available) to the Stock Exchange;

(iii) as there is no independent non-executive Director ordinarily resident in Hong Kong upon [**REDACTED**], we have appointed the Compliance Adviser pursuant to Rule 3A.19 and Rule 19A.05 of the Listing Rules, which has access at all times to our authorized representatives, Directors (including the independent non-executive Directors), senior management and other officers of our Company; and will act as an additional channel of communication with the Stock Exchange in addition to the authorized representatives of our Company;

(iv) our Company will also appoint a legal adviser as to Hong Kong laws for our Company's compliance matters upon the [**REDACTED**]. Our legal adviser as to Hong Kong laws will be appointed for a consecutive period commencing from the [**REDACTED**] so long as our Company is [**REDACTED**] on the Stock Exchange; and

(v) meetings between the Stock Exchange and our Directors (including the independent non-executive Directors) could be arranged through our authorized representatives, the Compliance Adviser, or directly with our Directors (including the independent non-executive Directors) through electronic means within a reasonable time frame. We will promptly inform the Stock Exchange of any changes of our authorized representatives and/or the Compliance Adviser.

Accordingly, our Company will not appoint an additional independent non-executive Director who ordinarily resides in Hong Kong upon [**REDACTED**]. Alternatively, our Company undertakes to comply with Rule 19A.18(1) of the Listing Rules and appoint an independent non-executive Director who ordinarily resides in Hong Kong at its forthcoming annual general meeting expected to be held in the first quarter of 2023.

[**REDACTED**]

Pursuant to Rule 8.08 of the Listing Rules, there must be an open market in the securities for which listing is sought and a sufficient public float of an issuer's listed securities shall be maintained. This normally means that (i) at least 25% of the issuer's total issued share capital must at all times be held by public; and (ii) where an issuer has more than one class of securities apart from the class of securities for which listing is sought, the total securities of the issuer held by public (listed on all regulated market(s) including the Stock Exchange) at the time of listing must be at least 25% of the issuer's total issued share capital. However, the class of securities for which listing is sought must not be less than 15% of the issuer's total issued share capital and must have an expected market capitalization at the time of listing of not less than HK$10 billion.

We have applied to the Stock Exchange to request the Stock Exchange to exercise its discretion under Rule 8.08(1)(d) of the Listing Rules, and the Stock Exchange [has granted] our Company a waiver from strict compliance with the requirements of Rule 8.08(1)(a) of the Listing Rules, pursuant to which the [**REDACTED**] of the Company may fall below 25% of the issued share capital of the Company (assuming the [**REDACTED**] is not exercised) or such higher percentage of Shares held by the [**REDACTED**] (if the [**REDACTED**] is fully or partially exercised).

The Stock Exchange [has] agreed to grant the requested waiver on the conditions that:

(i). the minimum [**REDACTED**] of the Company should be at the highest of (a) [**REDACTED**]% of the Company's total issued share capital; (b) such percentage of Shares held by the [**REDACTED**] immediately after the completion of the [**REDACTED**] (assuming that the [**REDACTED**] is not exercised); and (c) such percentage of Shares held by the [**REDACTED**] after the exercise of the [**REDACTED**], provided that the highest of (a), (b) and (c) above is below the minimum [**REDACTED**] requirement of 25% under Rule 8.08(1)(a) of the Listing Rules;

(ii). we will make appropriate disclosure of the lower percentage of [**REDACTED**] required by the Stock Exchange in this document;

(iii). we will as soon as practicable announce the percentage of Shares held by the [**REDACTED**] immediately after completion of the [**REDACTED**] (but before the exercise of the [**REDACTED**]), such that the public will be informed of the minimum [**REDACTED**] requirement applicable to the Company;

(iv). we will confirm sufficiency of [**REDACTED**] in the successive annual reports of the Company after [**REDACTED**];

(v). we will implement appropriate measures and mechanisms to ensure continual maintenance of the minimum percentage of **[REDACTED]** prescribed by the Stock Exchange; and

(vi). we will continue to comply with Rules 8.08(2) and 8.08(3) of the Listing Rules.

EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1) IN RELATION TO PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

According to Rule 4.04(1) of the Listing Rules, the accountants' report contained in the document must include, among others, the results of the company in respect of each of the three financial years immediately preceding the issue of the document or such shorter period as may be acceptable to the Stock Exchange.

According to Rule 18A.06 of the Listing Rules, an eligible biotech company shall comply with Rule 4.04 of the Listing Rules modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years," as the case may be.

According to section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the document shall include an accountants' report which contains the matters specified in the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

According to paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in the document a statement as to the gross trading income or sales turnover (as the case may be) of our Company during each of the three financial years immediately preceding the issue of the document as well as an explanation of the method used for the computation of such income or turnover and a reasonable breakdown of the more important trading activities.

According to paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in the document a report prepared by our Company's auditor with respect to profits and losses and assets and liabilities of our Company in respect of each of the three financial years immediately preceding the issue of the document.

According to section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interest of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or is otherwise unnecessary or inappropriate.

Accordingly, we have applied to the SFC for a certificate of exemption from strict compliance with the requirements under section 342(1) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance. The SFC [has] granted a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, exempting our company from strict compliance with the requirements of paragraph 27 of part I and paragraph 31 of part II of the Third Schedule of the Companies

(Winding Up and Miscellaneous Provisions) Ordinance on the conditions that the particulars of the exemption are set forth in this document and this document will be issued on or before [August 29, 2022].

The application to the SFC for a certificate of exemption from strict compliance with the requirements under section 342(1) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance was made on the following grounds:

(a) our Company is primarily engaged in developing, manufacturing and commercializing high quality biologics in China and overseas, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;

(b) the Accountants' Report for each of the two financial years ended December 31, 2020 and 2021 and the six months ended June 30, 2022 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;

(c) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements;

(d) given that Chapter 18A of the Listing Rules provide that the minimum track record period for biotech companies in terms of financial disclosure is two years, strict compliance with the requirements of section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company;

(e) our Directors and the Joint Sponsors confirm that after performing all due diligence work which they consider appropriate, up to the date of this document, there has been no material adverse change to the financial and trading positions or prospects of our Company since June 30, 2022 (immediately following the date of the latest audited statement of financial position in the Accountants' Report set out in Appendix I to this document) to the date of this document and there has been no event which would materially affect the information shown in the Accountants' Report as set out in Appendix I to this document and the section headed "Financial Information" in this document and other parts of the document; and

(f) our Directors are of the view that the Accountants' Report covering the two years ended December 31, 2020 and 2021 and the six months ended June 30, 2022 included in this document have already provided the potential investors with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company, and our Directors confirm that all information which is necessary for the investing public to make an informed assessment of our Company's business, assets and liabilities, financial position, trading position, management and prospects has been included in this document. Therefore the exemption would not prejudice the interest of the investing public.

[**REDACTED**]

[REDACTED]

[**REDACTED**]

[REDACTED]

[REDACTED]

[**REDACTED**]

[**REDACTED**]

DIRECTORS

Name	Residential Address	Nationality
Executive Directors		
Ms. Jiang Hua (姜華)	Room 101, No. 116 Gubei Xincheng Lane 511, Wuzhong Road Shanghai China	Chinese
Dr. Dou Changlin (竇昌林)	6-1-1202 Zhonghai Ziyu Residence Laishan District Yantai, Shandong Province China	American
Non-executive Directors		
Dr. Li Youxin (李又欣)	7-2-102, Xinghaiwan Community Laishan District Yantai, Shandong Province China	German
Mr. Liu Yuanchong (劉元沖)	No. 1, Unit 1, Building 17 Taiwan Village Laishan District Yantai, Shandong Province China	Chinese
Ms. Li Li (李莉)	No. 302, Unit 2, Building 11 Yulongshan No. 1016 Zhulin Road Zhifu District Yantai, Shandong Province China	Chinese
Mr. Chen Jie (陳杰)	No. 79, Lane 86 Yehui Road Zhaoxiang Town Qingpu District Shanghai China	Chinese

Name	Residential Address	Nationality
Independent non-executive Directors		
Mr. Liu Zhengjun (劉正軍)	No. 76, Lane 3588 Dushi Road Minhang District Shanghai China	Chinese
Mr. Shi Luwen (史錄文)	No. 12, 6th Floor Building 25 38 Xueyuan Road Haidian District Beijing China	Chinese
Mr. Dai Jixiong (戴繼雄)	Room 1101, No. 4 Lane 101, Rende Road Yangpu District Shanghai China	Chinese

SUPERVISORS

Name	Residential Address	Nationality
Ms. Zhang Xiaomei (張曉玫)	No. 907, 6 Gaoerfu Road Muping District Yantai, Shandong Province China	Chinese
Ms. Ning Xia (寧夏)	2-1-502 Fujia Community Zhifu District Yantai, Shandong Province China	Chinese
Ms. Liu Xiangjie (劉祥杰)	No. 202, Unit 1 Building 3 Poly Aishanghai Haibo Road Laishan District Yantai, Shandong Province China	Chinese

For further information regarding our Directors and Supervisors, please see "Directors, Supervisors and Senior Management" of this document.

OTHER PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

UBS Securities Hong Kong Limited
52/F, Two International Finance Centre
8 Finance Street
Central
Hong Kong

Essence Corporate Finance (Hong Kong) Limited
39/F, One Exchange Square
Central
Hong Kong

[**REDACTED**]

Legal advisers to our Company	*As to Hong Kong and United States laws:* **Allen & Overy** 9th Floor, Three Exchange Square Central Hong Kong *As to PRC laws:* **Commerce & Finance Law Offices** 12–14th Floor, China World Office 2 No. 1 Jianguomenwai Avenue Beijing, 100004 China
Legal advisers to the Joint Sponsors and the [REDACTED]	*As to Hong Kong and United States laws:* **Ashurst Hong Kong** 11/F, Jardine House 1 Connaught Place Central Hong Kong *As to PRC law:* **Jingtian & Gongcheng** 34/F, Tower 3, China Central Place 77 Jianguo Road Chaoyang District Beijing China
Auditor and reporting accountant	**Ernst & Young** *Certified Public Accountants* *Registered Public Interest Entity Auditor* 27/F, One Taikoo Place 979 King's Road Quarry Bay Hong Kong
Compliance adviser	**Maxa Capital Limited** Unit 1908, Harbour Center 25 Harbour Road Wanchai Hong Kong
Industry consultant	**Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.** Room 2504, Wheelock Square 1717 West Nanjing Road Jing'an District, Shanghai China

[REDACTED]

CORPORATE INFORMATION

Headquarters in the PRC	No. 39 Keji Avenue High-Tech Industrial Development Zone Yantai, Shandong Province China
Registered office in the PRC	No. 39 Keji Avenue High-Tech Industrial Development Zone Yantai, Shandong Province China
Principal place of business in Hong Kong	5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Company's website address	**www.boan-bio.com** *(information on this website does not form part of this document)*
Company secretary	Ms. Lai Siu Kuen (黎少娟) *(HKCGI, CGI)* 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Authorized representatives	Ms. Jiang Hua (姜華) Room 101, No. 116 Gubei Xincheng Lane 511, Wuzhong Road Shanghai China Ms. Lai Siu Kuen (黎少娟) 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Audit Committee	Mr. Dai Jixiong (戴繼雄) *(Chairperson)* Mr. Liu Yuanchong (劉元沖) Mr. Liu Zhengjun (劉正軍)
Remuneration Committee	Mr. Liu Zhengjun (劉正軍) *(Chairperson)* Ms. Li Li (李莉) Mr. Dai Jixiong (戴繼雄)

Nomination Committee	Mr. Shi Luwen (史錄文) *(Chairperson)* Ms. Li Li (李莉) Mr. Liu Zhengjun (劉正軍)
Strategy Committee	Ms. Jiang Hua (姜華) *(Chairperson)* Dr. Dou Changlin (竇昌林) Mr. Shi Luwen (史錄文)
	[REDACTED]
Principal banks	**Industrial and Commercial Bank of China Limited** **Yantai Laishan Branch** No. 108-103 Yingchun Avenue Laishan District Yantai, Shandong Province China
	China Everbright Bank Co., Ltd. **Yantai Laishan Branch** 1/F Runhua Building No. 177 Yingchun Avenue Laishan District Yantai, Shandong Province China
	China Merchants Bank Co., Ltd. **Yantai Branch** No. 66 Zhujiang Road Economic and Technological Development Zone Yantai, Shandong Province China
	Bank of America **Wakefield Branch** 2 Smith Street Wakefield, MA 01880 United States of America
	Citibank N.A., Singapore Branch 8 Marina View #16-01, Asia Square Tower 1 Singapore 018960

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the* [REDACTED]. *The information from official government sources has not been independently verified by us, the Joint Sponsors, the* [REDACTED], *the* [REDACTED], *the* [REDACTED], *the* [REDACTED], *the* [REDACTED], *the* [REDACTED], *any of their respective directors and advisers, or any other persons or parties involved in the* [REDACTED], *and no representation is given as to its accuracy.

OVERVIEW OF THE GLOBAL BIOLOGICS MARKET

Biologics are pharmaceutical products manufactured using biological methods and sources and can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. The major types of biologics include antibodies, fusion proteins, ADCs, recombinant proteins, vaccines, gene therapies and cell therapies.

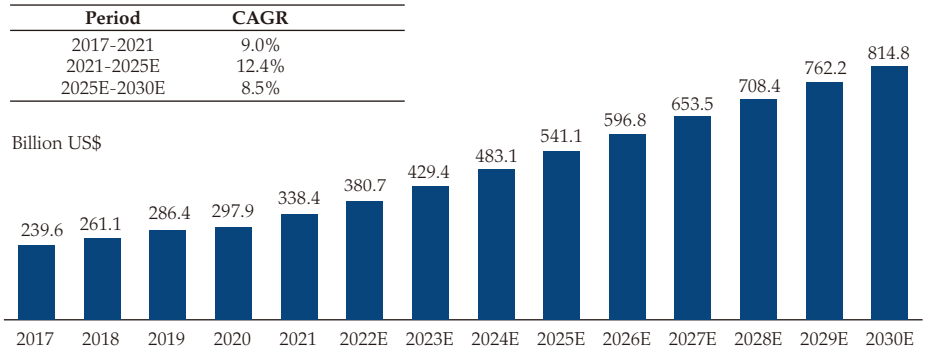
Top 10 drugs in terms of sales revenue globally

Biologic drugs are currently among many of the top-selling pharmaceutical products in the world. According to the Frost & Sullivan Report, the top-10 selling drugs globally in 2021 had combined sales revenue of US$156.8 billion. Of these top-10 drugs, five were biologics including Humira®, Keytruda®, Eylea®, Stelara® and Opdivo®, accounting for sales revenue of US$21.3 billion, US$17.2 billion, US$9.2 billion, US$9.1 billion and US$8.5 billion, respectively.

Global biologics market

The global biologics market in terms of sales revenue grew at a CAGR of 9.0% from US$239.6 billion in 2017 to US$338.4 billion in 2021. This trend is expected to continue in the coming years with the global biologics market expected to grow at a CAGR of 10.3% from 2021 to 2030, reaching US$814.8 billion in 2030. The following diagram illustrates the size of the global biologics market from 2017 to 2021 and the estimated market size from 2022 to 2030:

Global Biologics Market Size and Forecast, 2017-2030E



Source: Frost & Sullivan Report

Entry barriers to the global biologics market

According to the Frost & Sullivan Report, key entry barriers to the global biologics markets include the following:

- *Know-how in R&D, Manufacturing and Commercialization:* Biologics are large complex molecules consisting of a combination of proteins, peptides, nucleic acids, sugars, or other cellular structures, produced within living cells. The fragility of macromolecules and the sensitivity of living cells that produce biologics create complex technical requirements for the R&D and manufacturing of biologics. In addition, the large size and complexity of the biologic molecule increase the challenge for quality control to develop appropriate test methods for analysis of these products.

- *Heavy Capital Investment:* With complex structure and large timescale of research and development, the development process of biological drugs is more complicated than chemical drugs, including designing cell lines, optimizing the shake flask process, purification process, formulation process, etc. Large-scale biologics manufacturing facilities require US$200 million to US$700 million or more to build, compared with similar-scale small-molecule facilities that may cost just US$30 million to US$100 million. Besides, the R&D of biologics is uncertain. Compared with the development of chemical drugs, the R&D of biologics requires heavier capital investment.

- *Stringent Regulation:* Currently, the approval for biologics generally involves a more complex registration process, including requirements for more comprehensive clinical data. As applicants progress through clinical trials and to commercialization, the regulatory requirements will become increasingly stringent. Due to the nature of biologics, which are produced by living cells, the process as well as the product must be validated and strictly monitored against critical quality attributes ("**CQAs**") throughout the manufacturing process, not just at the end as for chemistry-based drugs. Regulatory compliance is an ongoing process, and applicants are expected to be in close communications with the regulator. These stringent regulatory challenges and considerations create a high entry barrier to the biologics market.

- *Commercialization:* Biologics are complex and costly to develop and manufacture, contributing to higher pricing than small molecule drugs. Manufacturers of biologics need to demonstrate the benefits relative to the costs for successful commercialization, which is increasingly difficult under competing biological therapies and leaner budgets of payers. Although biosimilars have the price advantage, it will take time for clinicians to trust the clinical efficacy and safety of a new drug, especially due to concerns around immunogenicity, which hinders market adoption. In addition, many biologics have the same indications or are developed based on similar methods. Under this circumstance, potential biosimilar manufacturers are often faced with uncertainties about the competitive response by existing manufacturers of the biologics and other biosimilars, which is a barrier to successful commercialization.

- *High Requirement in Manufacturing and Supply Chain Management:* Establishing biologics development capabilities and facilities, in particular the clinical and commercial manufacturing facilities, are highly capital intensive and time-consuming. For example, a biologics developer will have to build a facility approximately three to five years ahead in anticipation of product approval and launch. Meanwhile, supply chain management is also critical. Because biological drugs are sensitive, it requires very specific packaging, containment, and delivery to maintain efficacy and safety. The significant upfront cost, the lengthy process involved in biologics discovery, development, and commercial manufacturing, together with the high requirement of supply chain management create entry barriers for small companies and new market entrants.

- *Difficult to Replicate Compared to Small-molecule Drugs:* Biologics usually have large and complex molecular structures, which may be more easily influenced in the manufacturing process compared with small-molecule chemical drugs. Any slight difference in the structure will affect the safety and efficacy profile of biologics, making biologics difficult to replicate.

- *Long-term and Complex Development Process:* The production process of chemical drugs is relatively well defined, which allows these drugs to be produced in uniform large quantities. Biologics, however, have a complex production process that tends to yield small quantities. It is difficult to scale up biologics from laboratory quantities used for early analysis and preclinical testing to larger-scale batches and maintain product purity and batch-to-batch equivalence. The complexity in development and production makes the development process of biologics time-consuming.

The entry barrier for biosimilars is lower as compared to innovative drugs, mainly because biosimilars do not have patent protection that grants market exclusivity, and when the commercialization of biosimilars is allowed, the patent of reference drug will have expired by then. Thus, the market participants of biosimilars including us will face fiercer competition.

Market trends and key growth drivers of the global biologics market

According to the Frost & Sullivan Report, the key market trends and key growth drivers of the global biologics market include the following:

- *Efficacy of biologics:* Because biologics such as fusion proteins and monoclonal antibodies can specifically bind to designated antigens, they have been shown to have promising efficacy when used to treat cancer and autoimmune diseases, with high specificity, faster onset and fewer side effects. Such superior efficacy of biologics results in growing acceptance among patients and doctors, which stimulates demand and drives market growth.

- *Development in biotechnology and increasing investment in R&D:* The application of biotechnology in pharmaceutical science has brought a series of breakthroughs in the development of new biologics. For instance, as antibody-drug technology continues to evolve, antibody drugs have generated many innovative strategies, such as dual antibodies and ADCs. The developments in biotechnology may also be able to increase the production yield of biologics, leading to substantially lower production costs. The global research and development spending on biologics amounted to USD132.4 billion in 2017 and USD170.9 billion in 2021 and is estimated to reach USD237.2 billion in 2030. Global research and development investment for biologics is expected to increase in the future and is expected to bring more products into the market. The development in biotechnology and the continuous launch of new products will further drive the growth of the global biologics industry.

- *Increasingly more biological drug approvals:* From 2000 to 2008 and from 2009 to 2017, FDA approved 15 and 47 novel biologics respectively, representing 7.2% and 15.6% of the new drug approvals. But from 2018 to 2021, within just four years, FDA approved 57 novel biologics already. This shows an increasingly higher number of biologics approvals and indicates a great room for growth in the global biologics market.

OVERVIEW OF CHINA BIOLOGICS MARKET

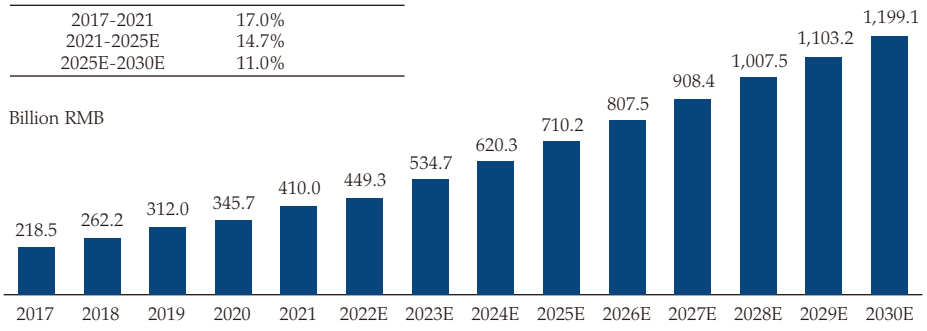
Driven by a growing but underserved demand of the cancer patient population, increasing affordability and healthcare awareness, favorable government policies and increased capital investment in research and development, China biologics market has experienced rapid growth in the past few years, faster than the global average.

China biologics market

China biologics market in terms of sales revenue grew from RMB218.5 billion in 2017 to RMB410.0 billion in 2021, representing a CAGR of 17.0%. The market is expected to further grow at a CAGR of 12.7% from 2021 to 2030, reaching RMB1,199.1 billion in 2030. The following diagram illustrates the size of China biologics market from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Biologics Market Size and Forecast, 2017-2030E

Period	CAGR
2017-2021	17.0%
2021-2025E	14.7%
2025E-2030E	11.0%



Source: Frost & Sullivan Report

Therapeutic antibody market size and forecast

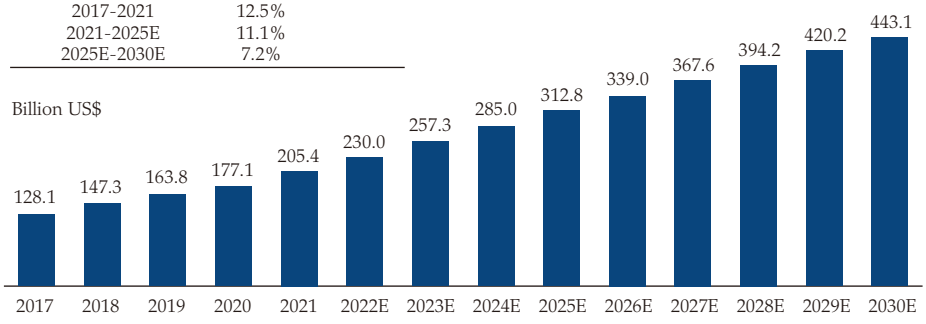
The therapeutic antibody market consists of the market for monoclonal antibodies, bispecific antibodies and ADC drugs. Transgenic mice technology and phage display technology are the technology platforms for fully human antibodies. From 2015 to 2021, the NMPA approved 21 innovative fully human antibodies and FDA approved 28 innovative fully human antibodies. Transgenic mice is more commonly used than phage display as the technology platform for fully human antibodies. Representative approved innovative fully human antibodies under the transgenic mice technology include Tepezza and Aimovig. Representative approved innovative fully human antibodies under the phage display technology include Ebanga and Gamifant. Bispecific antibodies are developed under different technologies, including the bispecific T-cell engager technology, dual checkpoint blockade technology and dual signaling inhibitions technology. For example, BLINCYTO (blinatumomab) is the approved bispecific antibody using the bispecific T-cell engager technology. ADC drugs developed under the ADC technology can be categorized into three generations. Representative approved first-generation ADCs include Mylotarg. Representative approved second-generation ADCs include Adcetris and Kadcyla, which use different linkers to avoid the limitation

and failure of Mylotrag and increased potency of cytotoxicity. However, these second-generation ADCs usually randomly combine cytotoxic drugs with lysine or cysteine residues on the antibody to produce different pharmacokinetic properties. Third-generation ADCs are further improved in terms of factors such as treatment index and linker plasma stability and have site-specific conjugation. Representative approved third-generation ADCs include Polivy and Padcev.

The global therapeutic antibody market grew from US$128.1 billion in 2017 to US$205.4 billion in 2021, representing a CAGR of 12.5%. The market is expected to further grow at a CAGR of 8.9% from 2021 to 2030, reaching US$443.1 billion in 2030. The following diagram illustrates the size of global therapeutic antibody market from 2017 to 2021 and the estimated market size from 2022 to 2030:

Global Therapeutic Antibody Market Size and Forecast, 2017-2030E

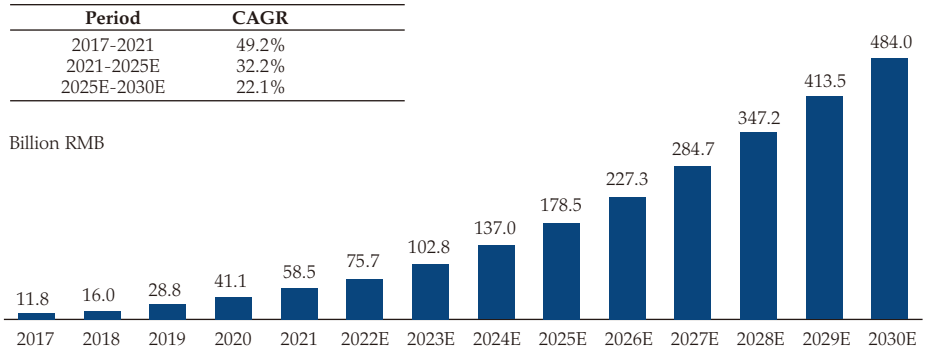
Period	CAGR
2017-2021	12.5%
2021-2025E	11.1%
2025E-2030E	7.2%



Source: Frost & Sullivan Report

China therapeutic antibody market grew from RMB11.8 billion in 2017 to RMB58.5 billion in 2021, representing a CAGR of 49.2%. The market is expected to further grow at a CAGR of 26.5% from 2021 to 2030, reaching RMB484.0 billion in 2030. The following diagram illustrates the size of China therapeutic antibody market from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Therapeutic Antibody Market Size and Forecast, 2017-2030E



Source: Frost & Sullivan Report

Market trends and key growth drivers of China biologics market

According to the Frost & Sullivan Report, the key market trends and key growth drivers of the China biologics market include the following:

- *Growing chronic disease incidence:* Driven by unhealthy lifestyles, pollution, and the aging population, the number of patients with chronic diseases in China continues to expand. For example, in the therapeutic areas of Company's products, total annual cancer incidence in China increased from 4,172 thousand in 2017 to 4,688 thousand in 2021, and this number is expected to reach 5,812 thousand in 2030. In the area of metabolic diseases, prevalence is also expected to increase. Biological drugs have excellent clinical effects on many chronic diseases, including cancer and diabetes, and the huge patient population pool will further drive market growth.

- *Increasing R&D investments:* The biologics industry is capital-intensive and requires heavy investment in research and development. In China, the research and development spending on biologics increased from RMB76.2 billion to RMB142.0 billion, with a CAGR of 16.8% from 2017 to 2021. R&D expenditure on biologics is expected to reach RMB308.8 billion in 2030, indicating a promising future with more biologics approved and brought to the market.

- *Regulatory reform and favorable government policies:* China has established a set of regulations and policies to support the development of its biologics market. Notably, in October 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), which aims to improve the regulatory regime for the biologics industry, encourage the technological innovation for new drugs and enhance the competitiveness of the biologics industry. With respect to biosimilars, the Center for Drug Evaluation (CDE) promulgated《生物類似藥相似性評價和適應症外推技術指導原則》, which puts forward clear regulatory requirements for product development and indication extrapolation for biosimilars. Such policies are beneficial to Company's products, which include innovative biologics and biosimilars.

- *Increasing affordability and healthcare awareness:* In China, the per capita disposable income has grown rapidly from RMB25,974 in 2017 to RMB35,128 in 2021. This increase in disposable income is reflected in the increase in healthcare expenditure, and this trend is expected to continue. In recent years, the inclusion of biologics into NRDL further increases accessibility and affordability of biologics. For example, some of Company's products such as bevacizumab and denosumab have already been included in the NRDL. Increasing affordability brought by NRDL inclusion along with increased health awareness would further drive market growth as sales volume is expected to increase. In addition, in November 2021, China's latest centralized drug procurement involved centralized purchase of insulin, which is the first biological drug involved in the centralized procurement program. After the centralized purchase, the average price cut and highest price cut are 48% and 74%, respectively, which sets an example for improvement in biologics affordability through centralized drug procurement. With the increasing biologics affordability and the improvement of health awareness, domestic demand for biological drugs will burgeon in the future.

Medical insurance in China

Medical insurance schemes provided by the PRC government, including urban and rural medical insurance, are the largest payors of pharmaceutical expenditures in China.

China's NRDL is managed by regulatory authorities such as the Ministry of Human Resources and Social Security and the National Healthcare Security Administration. The NRDL consists of two drug catalogues, namely Category A and Category B. Drugs that fall into Category A are fully reimbursable. Drugs with a higher price typically fall into Category B which generally require a 10% to 30% co-payment by patients. Inclusion in the NRDL typically results in a much higher sales volume and a significant sales growth despite a reduction in the price.

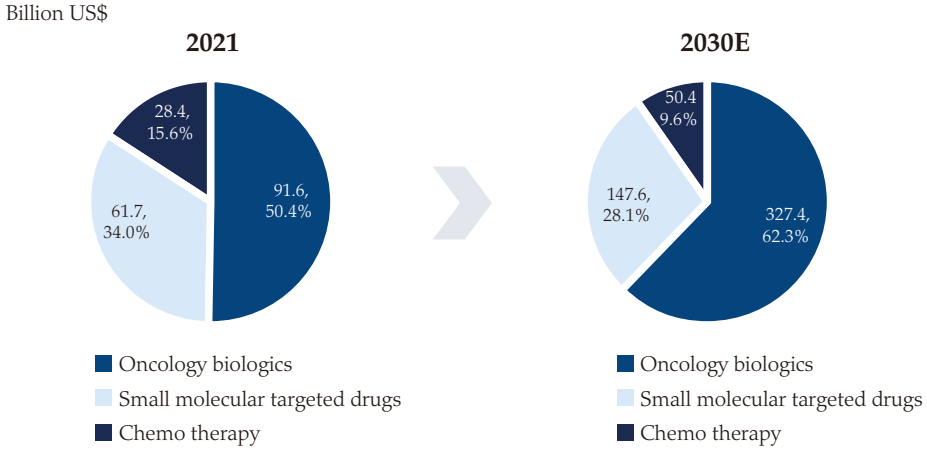
Historically, in terms of cancer treatment, only chemotherapy drugs were included in the NRDL, and the biologics oncology drug market was essentially a users' self-pay market. The PRC government has made significant efforts in enhancing the affordability of biologics. China's NRDL is managed by regulatory authorities such as the Ministry of Human Resources and Social Security and National Healthcare Security Administration. The NRDL (2021 edition) was published on December 3, 2021, with effect from January 1, 2022. There was a total of 74 new drugs added in the NRDL (2021 edition), with oncology as the top therapeutic area. As more biologics are included in the NRDL, the affordability of biologics is expected to increase which allows greater market access. Given the PRC government's increasing attention to major public health issues, it is expected that more innovative drugs will be included in the NRDL in the future.

Furthermore, centralized procurement in China has strong bargaining power over pricing of biopharmaceutical products. See "Risk Factors — Risks relating to the commercialization of our drug candidates — Even if we are able to commercialize any drug candidates, the drugs may become subject to national or other third-party reimbursement practices, healthcare reform initiatives or unfavorable pricing regulations, which could harm our business" for further details.

ONCOLOGY BIOLOGICS MARKET

In 2021, oncology biologics accounted for 50.4% of the global oncology drugs market in terms of sales revenue. The market share is estimated to increase to 62.3% in 2030. The following diagram illustrates the breakdown of the sales of the global oncology drugs in 2021 and the estimated breakdown of the sales of the global oncology drugs in 2030:

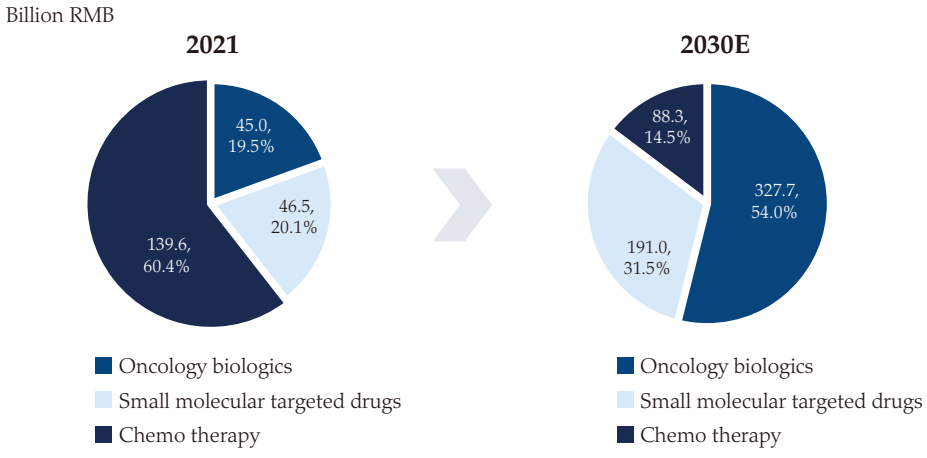
Breakdown of Global Oncology Drugs, 2021 and 2030E



Source: Frost & Sullivan Report

In 2021, oncology biologics accounted for 19.5% of the total oncology drugs market in China in terms of sales revenue. The market share is estimated to increase to 54.0% in 2030. Historically, due to the limited availability and affordability of oncology biologics, the share of biologics in oncology treatment was poor. Although the revolution of NRDL and improvement in review efficiency strive to change such situation, it still takes time to gradually achieve a relative increase in market share. In 2021, biologics share was approximately 19.5% while chemo therapy still dominated the oncology treatment with a share of 60.4%. With the expanding inclusion of biologics into NRDL, it is believed that advanced therapies will gain increasing share. This is especially evident in the fast development of immuno-oncology therapies, as China has more PD-1/L1 monoclonal antibody approvals than counterparts in developed countries. This will contribute to a large portion of market growth, driving the biologics share to achieve approximately 54.0% in 2030. The following diagram illustrates the breakdown of the sales of China oncology drugs in 2021 and the estimated breakdown of the sales of China oncology drugs in 2030:

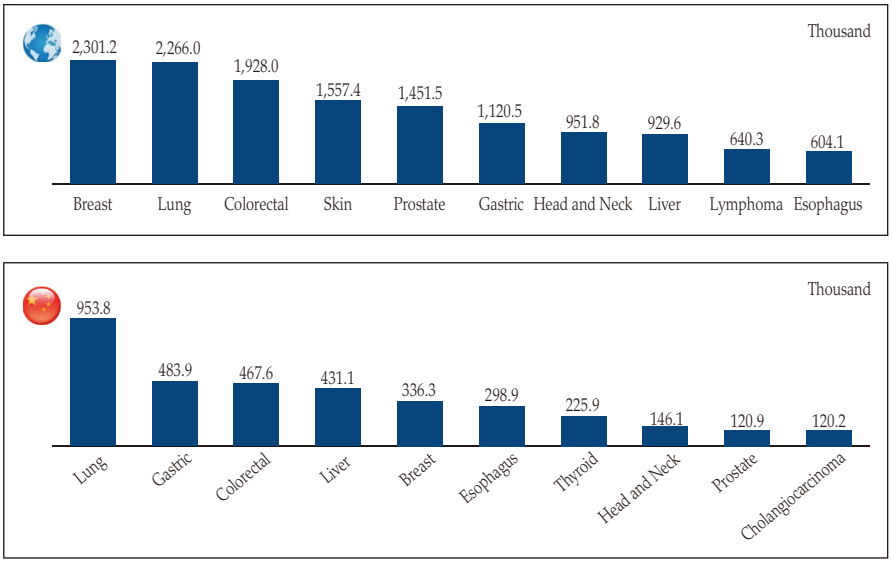
Breakdown of China Oncology Drugs, 2021 and 2030E



Source: Frost & Sullivan Report

Top cancer types in China and global markets

China and the world have demonstrated different profile of top 10 cancers in terms of new cases in 2021, but both share some major types of cancers in their top-10 lists such as lung, gastric and liver cancers. The following diagrams illustrate the top 10 cancers globally and in China by new cases for 2021:



Source: Frost & Sullivan Report

Oncology biosimilars market

Bevacizumab market

Bevacizumab is designed to directly bind to VEGF extracellularly to prevent interaction with VEGF receptors ("**VEGFRs**") on the surface of endothelial cells, and thereby inhibiting VEGF's angiogenic activity. By exerting both anti-vascular and anti-angiogenesis effect on vessel surrounding the tumor, bevacizumab can result in both reduction of tumor size and inhibition of tumor growth.

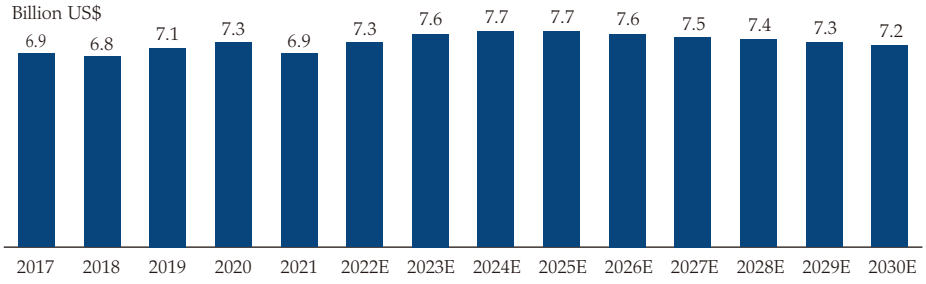
We independently develop Boyounuo® (BA1101), bevacizumab injection and an anti-VEGF humanized monoclonal antibody injection as well as a biosimilar to Avastin®. In April 2021, the NMPA approved Boyounuo® (BA1101) for the treatment of advanced, metastatic or recurrent non-small cell lung cancer and metastatic colorectal cancer. In July 2021, the NMPA further approved Boyounuo® (BA1101) for the treatment of recurrent glioblastoma. In February 2022, the NMPA further approved Boyounuo® (BA1101) for the treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer.

Market size

According to the Frost & Sullivan Report, global bevacizumab market size increased from US$6.9 billion in 2017 to US$6.9 billion in 2021, with a CAGR of 0.2%, and is expected to continue to increase to US$7.2 billion in 2030, with a CAGR of 0.5% from 2021 to 2030. The following diagram illustrates the size of the global bevacizumab market from 2017 to 2021 and the estimated market size from 2022 to 2030:

Global Bevacizumab Market Size and Forecast, 2017-2030E

Period	CAGR
2017-2021	0.2%
2021-2025E	2.5%
2025E-2030E	-1.1%

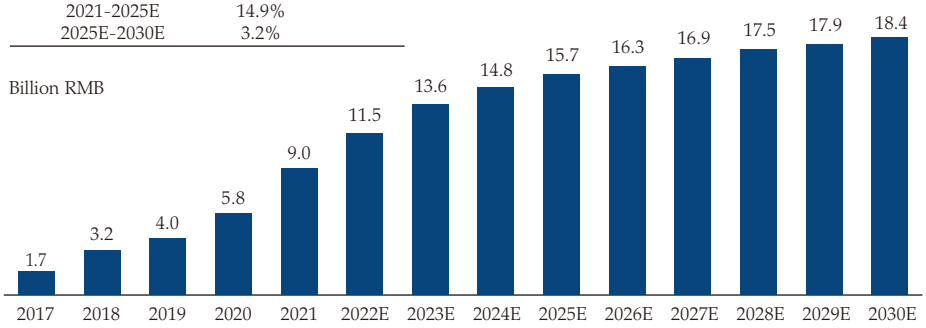


Source: Frost & Sullivan Report

According to the Frost & Sullivan Report, China bevacizumab market size increased from RMB1.7 billion in 2017 to RMB9.0 billion in 2021, with a CAGR of 51.4%, and is expected to increase to RMB18.4 billion in 2030, with a CAGR of 8.3% from 2021 to 2030. The following diagram illustrates the size of China bevacizumab market from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Bevacizumab Market Size and Forecast, 2017-2030E

Period	CAGR
2017-2021	51.4%
2021-2025E	14.9%
2025E-2030E	3.2%



Source: Frost & Sullivan Report

Competitive landscape

As of the Latest Practicable Date, there were nine NMPA approved bevacizumab in China, including the reference drug by Roche and eight domestic biosimilars, inclusive of Boyounuo® (BA1101), further details of which are set forth below:

Brand name	Generic name	Company	Initial NMPA approval	Indications	Annual cost per patient[1] (RMB)	2021 China sales revenue (million RMB)	NRDL
Avastin®	Bevacizumab	Roche	2010-02-26	mCRC Advanced metastatic or recurrent NSCLC Cervical cancer Recurrent glioblastoma Hepatocellular carcinoma Epithelial ovarian, fallopian tube, or primary peritoneal cancer	~180,000	3,299	According to the NRDL (2021 edition) (in effect on January 1, 2022), only bevacizumab (Avastin®) indicated for the treatment of mCRC, metastatic/recurrent NSCLC, recurrent glioblastoma and unresectable HCC are included in Category B.[3]
Ankeda®	Bevacizumab-QL1101	Qilu Pharma	2019-12-06	mCRC Advanced metastatic or recurrent NSCLC	~139,440	3,500	
BYVASDA®	Bevacizumab-IBI305	Innovent	2020-06-17	mCRC Advanced metastatic or recurrent NSCLC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer Hepatocellular carcinoma	~138,480	NA	
Boyounuo®	**Bevacizumab-BA1101**	**Our Group**	**2021-04-30**	**mCRC** **Advanced metastatic or recurrent NSCLC** **Recurrent glioblastoma** **Cervical cancer** **Epithelial ovarian, fallopian tube, or primary peritoneal cancer**	**~137,640**	**158.7**	
Airuituo (艾瑞妥)	Bevacizumab-BP102	Suzhou Suncadia	2021-06-22	mCRC Advanced metastatic or recurrent NSCLC Recurrent glioblastoma	~138,480	NA	
Pubeixi (普貝希)	Bevacizumab-BAT1706	Bio-Thera Solutions	2021-11-17	Advanced metastatic or recurrent NSCLC mCRC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer	~137,640	NA	
Beianting (貝安汀)	Bevacizumab-MIL60	Betta Pharma	2021-11-24	Advanced metastatic or recurrent NSCLC mCRC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer	NA	NA	
Hanbeitai	Bevacizumab-HLX04	Henlius Biotech	2021-11-30	Advanced metastatic or recurrent NSCLC mCRC	NA	NA	
Pusintin®	Bevacizumab-TAB008	Tot Biopharm	2021-11-30	Advanced metastatic or recurrent NSCLC mCRC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer Hepatocellular carcinoma	~137,040	NA	

Notes:

(1) Annual cost per patient varies by treatment regimen and the cost listed is before medical insurance reimbursement.

(2) Bevacizumab is recommended in combination with chemotherapy for up to six cycles followed by administration as a single agent for a total of up to 22 cycles or until disease progression; however, treatment cycle varies by patient condition and is subject to physician discretion.

(3) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

(4) NA means not applicable or public information is not available.

Source: Frost & Sullivan Report

Major patents for bevacizumab have expired including those in the United States in 2019, the EU in 2020 and China in 2018.

The dosage and administration of bevacizumab vary by indications such as the following examples. All the treatment is indicated in the approval label by each competent authority such as NMPA and mentioned in the clinical guidelines.

mCRC: As a first-line and second-line therapy for advanced mCRC, the recommended dose when bevacizumab is administered intravenously in combination with fluoropyrimidine-based chemotherapy is 5 mg/kg every two weeks, or 7.5 mg/kg every three weeks.

Advanced metastatic or recurrent NSCLC: As a first-line therapy for unresectable, advanced, recurrent or metastatic NSCLC, bevacizumab is administered at 15 mg/kg intravenously every three weeks in combination with platinum-based chemotherapy, followed by bevacizumab as a single agent.

Recurrent glioblastoma: As a first-line therapy for recurrent glioblastoma, bevacizumab is administered at 10 mg/kg intravenously every two weeks.

Epithelial ovarian, fallopian tube or primary peritoneal cancer: As a first-line therapy for epithelial ovarian, fallopian tube or primary peritoneal cancer, bevacizumab is administered at 15 mg/kg intravenously every three weeks in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent.

Cervical cancer: As a first-line therapy for cervical cancer, bevacizumab is administered at 15 mg/kg intravenously every three weeks in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.

Denosumab market

Osteoblasts express receptor activator of NF-κB ligand (RANKL), which binds to its receptor, RANK, on the surface of osteoclasts and their precursors. This regulates the differentiation of precursors into multinucleated osteoclasts and osteoclast activation. Osteoprotegerin (OPG) is secreted by osteoblasts and osteogenic stromal stem cells and protects the skeleton from excessive bone resorption by binding to RANKL and preventing it from interacting with RANK. Denosumab is a fully human monoclonal antibody that binds RANKL, preventing RANKL from activating RANK, its receptor on the osteoclast surface. With reduced RANK–RANKL binding, osteoclast formation, function and survival are inhibited, bone resorption decreases and bone mass increases.

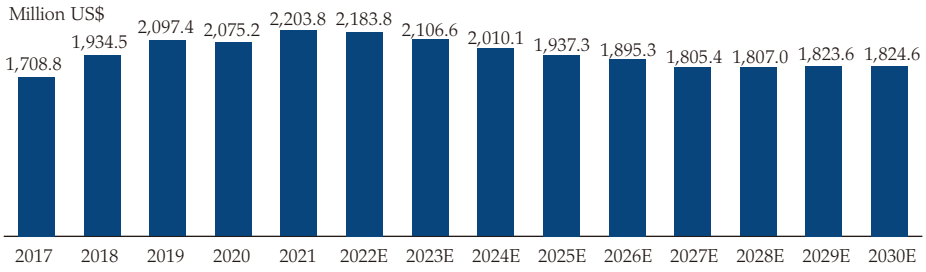
We independently develop BA1102, denosumab injection and a biosimilar to Xgeva®, which is currently under Phase 3 clinical trial in China.

Market size

According to the Frost & Sullivan Report, the global denosumab market size of Xgeva® and its biosimilars increased from US$1,708.8 million in 2017 to US$2,203.8 million in 2021, with a CAGR of 6.6%, and is expected to decrease to US$1,824.6 million in 2030. The decreasing trend of global denosumab market is due to the expected price erosion from biosimilar competition. However, the increase in sales volume due to the expected price erosion to a significant extent will compensate for the price drop. The following diagram illustrates the global denosumab market size of Xgeva® and its biosimilars from 2017 to 2021 and the estimated market size from 2022 to 2030:

Global Denosumab Market Size and Forecast (Xgeva® and its Biosimilars), 2017-2030E

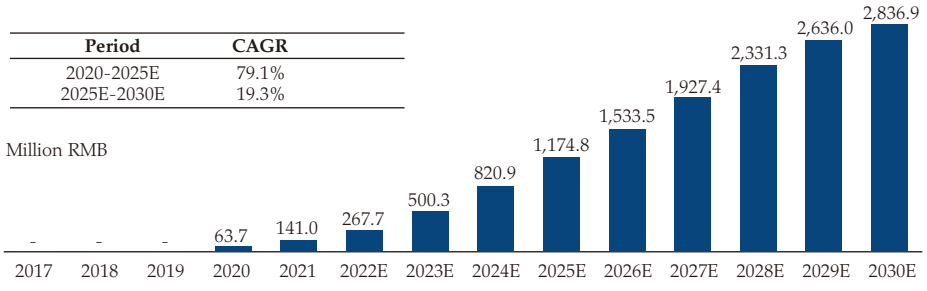
Period	CAGR
2017-2021	6.6%
2021-2025E	-3.2%
2025E-2030E	-1.2%



Source: Frost & Sullivan Report

According to the Frost & Sullivan Report, the sales revenue of denosumab market of Xgeva® and its biosimilars in China increased from nil in 2017 to RMB141.0 million in 2021, and is expected to increase to RMB2,836.9 million in 2030 with a CAGR of 39.6% from 2021 to 2030. Xgeva® is indicated for skeletal-related events in patients with bone metastases from solid tumors, skeletal-related events in patients with multiple myeloma and GCTB in China. Since global initial approval of Xgeva® by FDA in 2010, it has benefited thousands of patients globally. As more than 60% of the global sales revenue of Xgeva® was generated from the United States, it is reasonable to benchmark the 2030 China market estimation to U.S. clinical practice in 2020, when Xgeva® has been used clinically by more than 40 thousand patients, representing a penetration of approximately 16.0% in total patients of three indications. Assuming that China will reach the similar penetration rate in 2030 given the improving affordability by NRDL inclusion and price erosion from biosimilar competition, a total of 221.6 thousand patients will have the opportunity to use Xgeva®, generating a market of RMB2.8 billion in 2030 in China. The following diagram illustrates the China denosumab market size of Xgeva® and its biosimilars from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Denosumab Market Size and Forecast (Xgeva® and its Biosimilars), 2017-2030E



Source: Frost & Sullivan Report

Competitive landscape

Xgeva® (denosumab) has been launched in the United States, the EU and China, the details of which are set forth below. As of the Latest Practicable Date, there was no biosimilar to Xgeva® (denosumab) that had launched in any market.

Brand name	Generic name	Company	Region/authority	Initial approval date	Approved indications	Annual cost per patient	2021 global sales revenue	NRDL
Xgeva® 安加維 (reference drug)	Denosumab	Amgen	U.S./FDA	2010-11-19	• Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. • Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.	~US$34,294.1 (bone metastasis from solid tumors and multiple myeloma) ~US$39,570.2 (GCTB)	US$2.2 billion	–
		Amgen	EU/EMA	2011-07-13	• Prevention of skeletal related events in adults with advanced malignancies involving bone. • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.	~€24,000 (cost varies among countries)		–
		Amgen/ BeiGene	China/NMPA	2019-05-21	• Treatment of adults and skeletally mature adolescents (defined by at least one mature long bone and a weight ≥45 kg) with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. • Skeletal-related events in patients with bone metastases from solid tumors. • Skeletal-related events in patients with multiple myeloma.	~RMB13,780 (bone metastases from solid tumor and multiple myeloma) ~RMB15,900 (GCTB)		Category B(2)

Note:

(1) The median duration of treatment of Xgeva® is 12 months based on disclosure on FDA label, but the length of treatment for a patient is dependent on disease status and patient condition and is subject to physician discretion.

(2) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were two clinical-stage Xgeva® (denosumab) biosimilar candidates globally (outside of China). In China, there were six clinical-stage Xgeva® (denosumab) biosimilar candidates as of the same date, the details of which are set forth below:

Region	Drug name/code	Company	Phase	Indications	First posted date
China	**BA1102**	**Our Group**	**Phase 3**	**Bone metastases from solid tumors**	**2021-02-08**
	9MW0321	Jiangsu T-mab Bio-Pharma	BLA	Prevent skeletal-related events caused by bone metastases from solid tumors	2021-12-22
	QL1206	Qilu Pharma	BLA	Bone metastases from solid tumors	2021-08-30
	HS629	Hisun Pharma	Phase 1	Prevent skeletal-related events caused by bone metastases from solid tumors	2018-04-12
	HL05	Hualan Genetic	Phase 1	Prevent skeletal-related events caused by bone metastases from solid tumors	2020-02-26
	HS-20090	Jiangsu Hansoh Pharmaceutical/ Shanghai Hansoh BioMedical	Phase 3	Prevent skeletal-related events caused by bone metastases from solid tumors and multiple myeloma	2022-10-21
Europe	**BA1102[1]**	**Our Group**	**Phase 1**	**Bone metastases from solid tumors, GCTB**	**2020-10-20**
	MB09	mAbxience S.A	Phase 1	Healthy male	2022-03-28

Note:

(1) BA1102 is in the stage of Phase 1 clinical trial in the EU by virtue of the clinical trial conducted for BA6101 in the EU. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phase 1 and Phase 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®.

(2) For overseas biosimilars to enter the China market, data from overseas clinical trials can be accepted for BLA since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018.

Source: Frost & Sullivan Report

Major patents for denosumab will expire in the United States in 2025 and in the EU predominantly in 2025. Major patents for denosumab in China have expired in June 2022.

The dosage and administration of denosumab vary by indication such as the following examples.

Bone metastases from solid tumors: In addition to specific chemotherapy and targeted therapy for primary tumors, major domestic and foreign guidelines recommend denosumab or bisphosphonates to reduce and delay the occurrence of SREs. Generally, as a first-line therapy for bone metastases from solid tumors, denosumab is administered at 120 mg every four weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen.

GCTB: Denosumab is the only regimen for the treatment of unresectable GCTB or when surgical resection is likely to result in severe morbidity. Denosumab is administered at 120 mg every four weeks with additional 120 mg doses on days eight and 15 of the first month of therapy as a subcutaneous injection in the upper arm, upper thigh, or abdomen.

Nivolumab market

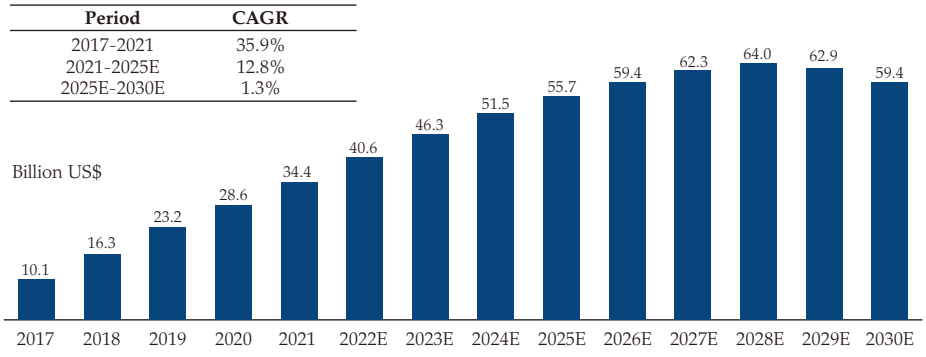
Opdivo® (nivolumab) by BMS is a programmed cell death 1 ("**PD-1**") receptor blocking antibody that is used alone or in combination with other medicines that works with the immune system to interfere with the growth and spread of cancer cells in the body. PD-1 is an important immunosuppressive molecule with two ligands, PD-L1 and PD-L2. Tumor cells can use the PD-L1 produced on their cell surface to escape T cell destruction. When PD-1 on the surface of T cells recognizes PD-L1 on the surface of the tumor, it can transmit inhibitory signals. T cells will be unable to detect tumor cells or send out attack signals to them due to its inhibitory effect. The tumor cells can grow and achieve immunity escape. After adding PD-1 or PD-L1 inhibitors, the PD-1 of T lymphocytes and the PD-L1 of tumor cells cannot be effectively combination, thereby breaking the tumor immune escape mechanism. Major patents for nivolumab will expire in December 2028, June 2030, and May 2026 in the United States, the EU and China, respectively.

We independently develop BA1104, a biosimilar to Opdivo® (nivolumab), which is a product candidate with PD-1 target.

Market size

According to the Frost & Sullivan Report, the global PD-1/L1-based antibody market size increased from US$10.1 billion in 2017 to US$34.4 billion in 2021, with a CAGR of 35.9%, and is expected to increase to US$59.4 billion in 2030, with a CAGR of 6.2% from 2021 to 2030. The following diagram illustrates the size of global PD-1/L1-based antibody market from 2017 to 2021 and the estimated market size from 2022 to 2030:

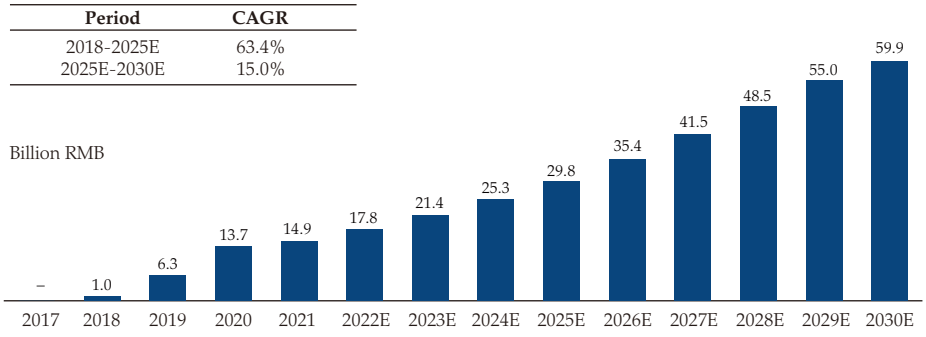
Global PD-1/L1-based Antibody Market Size and Forecast, 2017-2030E



Source: Frost & Sullivan Report

According to the Frost & Sullivan Report, the China PD-1/L1-based antibody market size increased from nil in 2017 to RMB14.9 billion in 2021, and is expected to increase to RMB59.9 billion in 2030, with a CAGR of 16.7% from 2021 to 2030. The following diagram illustrates the size of China PD-1/L1-based antibody market from 2017 to 2021 and the estimated market size from 2022 to 2030:

China PD-1/L1-based Antibody Market Size and Forecast, 2017-2030E



Source: Frost & Sullivan Report

Competitive landscape

As of the Latest Practicable Date, there was no clinical-stage biosimilars of Opdivo® globally (outside of China). In China, there were two clinical-stage biosimilars of Opdivo® as of the same date, the details of which are set forth below:

Drug name/code	Company	Indication	Phase	First posted date
CMAB819	Mabpharm	Recurrent/metastatic HNSCC following disease progression during or after platinum-based therapy	Phase 1	2020-09-14
BA1104	**Our Group**	**Melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma**	**Phase 1**	**2022-09-21**

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were seven PD-1/PD-L1 monoclonal antibodies approved globally, further details of which are set forth below:

Company	Generic name	Brand name	FDA approval month	EMA approval month	FDA approval Indications
Merck	Pembrolizumab	KEYTRUDA®	2014-09	2015-07	Melanoma, NSCLC, HNSCC, cHL, PMBCL, Urothelial carcinoma, Gastric cancer, Esophageal cancer, Cervical cancer, HCC, MCC, RCC, MSI-H/dMMR cancer, MSI-H/dMMR CRC, Endometrial carcinoma, TMB-H Cancer, CSCC, TNBC
BMS	Nivolumab	OPDIVO®	2014-12	2015-06	Unresectable or metastatic melanoma, Metastatic NSCLC, Malignant pleural mesothelioma, Advanced RCC, cHL, HNSCC, Urothelial carcinoma, MSI-H/dMMR CRC, HCC, Esophageal cancer, Gastroesophageal junction cancer and esophageal adenocarcinoma
Regeneron/ Sanofi	Cemiplimab	LIBTAYO®	2018-09	2019-06	NSCLC, BCC, Metastatic or locally advanced CSCC
GSK	Dostarlimab	JEMPERLI®	2021-04	2021-04	dMMR recurrent or advanced endometrial cancer or solid tumors
Roche	Atezolizumab	TECENTRIQ®	2016-05	2017-09	NSCLC, SCLC, HCC, Melanoma, urothelial carcinoma
Merck/Pfizer	Avelumab	BAVENCIO®	2017-03	2017-09	Metastatic MCC, Locally advanced or metastatic urothelial carcinoma, advanced RCC
Astra Zeneca	Durvalumab	IMFINZI®	2017-05	2018-09	Unresectable NSCLC, ES-SCLC, Biliary tract cancer, unresectable hepatocellular carcinoma

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were 10 PD-1 monoclonal antibodies approved in China. Opdivo® was the first PD-1/L1 monoclonal antibody approved for the treatment of gastric cancer in China. Further details are set forth below:

Generic name	Brand name	Company	Approval month	Approval indications	NRDL[1]
Nivolumab	Opdivo®	BMS	2018-06	Gastric cancer, Gastroesophageal junction cancer, Gastric adenocarcinoma (GAC), Esophageal cancer, NSCLC, HNSCC, Malignant pleural mesothelioma, Gastroesophageal junction adenocarcinoma	Not in list
Pembrolizumab	Keytruda®	MSD	2018-07	Unresectable metastatic melanoma, NSCLC, Esophageal cancer, CRC, HNSCC, Gastroesophageal junction cancer	Not in list
Toripalimab	Tuoyi®	Shanghai Junshi Biosciences	2018-12	Unresectable metastatic melanoma, NPC, Urothelial carcinoma, ESCC	Category B
Sintilimab	Tyvyt®	Innovent	2018-02	cHL, NSCLC, HCC, ESCC	Category B
Camrelizumab	AiRuiKa™	Suzhou Suncadia	2019-05	cHL, Advanced HCC, NSCLC, Advanced metastatic ESCC, NPC	Category B
Tislelizumab	Baize'an®	BeiGene	2019-12	cHL, HCC, NSCLC, Urothelial carcinoma, NPC, CRC, ESCC	Category B
Penpulimab	Annike®	Zhengda Tianqing Kangfang (Shanghai) Biomedical Technology	2021-08	cHL	Not in list
Zimberelimab	Yutuo®	Gloria Biosciences	2021-08	cHL	Not in list
Serplulimab	漢斯狀®	Shanghai Henlius Biotech	2022-03	Unresectable/MSI-H advanced solid tumors	Not in list
Pembrolizumab	普佑恒®	Chime Biologics (Leap)	2022-07	Unresectable/MSI-H advanced solid tumors	Not in list

Note:

(1) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were four PD-L1 monoclonal antibodies approved in China, further details of which are set forth below:

Generic name	Brand name	Company	Approval month	Approval indications	NRDL
Durvalumab	Imfinzi®	Astra Zeneca	2019-12	NSCLC, SCLC	Not in list
Atezolizumab	Tecentriq®	Roche	2020-02	HCC, NSCLC, SCLC	Not in list
Envafolimab	ENWEIDA®	Sichuan Kangrui Pharma	2021-11	dMMR/MSI-H advanced solid tumors	Not in list
Sugemalimab	Cejemly®	Cstone Pharma	2021-12	NSCLC	Not in list

Source: Frost & Sullivan Report

Oncology innovative drug market

Claudin 18.2 based antibody market

Claudin 18.2 (isoform 2 of Claudin 18) is encoded by CLDN18 genes, belongs to the Claudin protein family, and forms one of the important components of the tight cell junctions. Claudin 18.2 is a transmembrane protein and is highly expressed in tissues of multiple tumor types, especially those in the digestive system, thus making Claudin 18.2 a potential molecular target for treating certain malignant tumors. Clinical significance of Claudin 18.2 lies in its high molecular specificity and highly restricted expression in cancer cells as well as the ability to retain on malignant transformation. While Claudin 18.2 is highly expressed in cancer cells, it has very low expression in normal adult tissues, making it a potential treatment target for certain cancer types. Main indications of anti-Claudin 18.2 drugs include gastric cancer, pancreatic cancer, and gastroesophageal junction cancer. Main therapy types include: monoclonal antibody, bispecific antibody, ADC, CAR-T, etc.

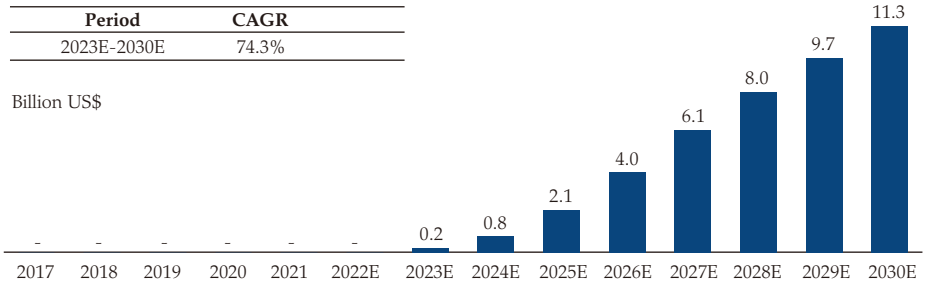
Gastric cancer is one of the most frequently occurring cancers in China and there is an obvious geographical distribution. China incidence of gastric cancer increased from 429.0 thousand in 2017 to 483.9 thousand in 2021 and is estimated to reach 622.4 thousand in 2030. With the trend of aging population, increasing obesity and diabetes, as well as chronic liver disease, the incidence of pancreatic cancer in China grows in recent years. The incidence of pancreatic cancer in China increased from 101.5 thousand in 2017 to 115.9 thousand in 2021 and is estimated to reach 155.8 thousand in 2030. China incidence of esophageal cancer increased from 262.9 thousand in 2017 to 298.9 thousand in 2021 and is estimated to further increase to 389.2 thousand in 2030, driven by the penetration of early screening and other factors.

We independently develop BA1105, which is a product candidate for the treatment of advanced gastric cancer, metastatic pancreatic cancer, and adenocarcinoma of the esophagogastric junction with Claudin 18.2 expression. It is under Phase 1 clinical trial in China. In addition, we independently develop BA1301, a product candidate for the treatment of gastric cancer, pancreatic cancer and esophageal cancer with Claudin18.2 expression.

Market size

There was no Claudin 18.2-based antibody marketed globally from 2017 to 2021 according to the Frost & Sullivan Report. The size of global Claudin 18.2-based antibody is expected to increase from US$200.0 million in 2023 to US$11.3 billion in 2030, with a CAGR of 74.3%. The following diagram illustrates the size of global Claudin 18.2-based antibody from 2017 to 2021 and the estimated market size from 2022 to 2030:

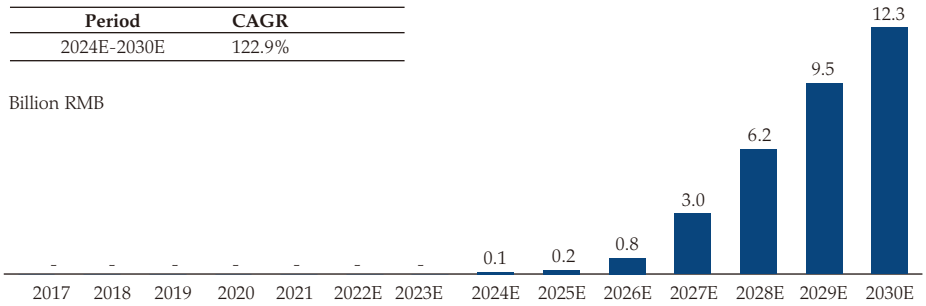
Global Claudin 18.2-based Antibody Market, 2017-2030E



Source: Frost & Sullivan Report

According to the Frost & Sullivan Report, there was no Claudin 18.2-based antibody marketed in China from 2017 to 2021. The size of China Claudin 18.2-based antibody is expected to increase from RMB100.0 million in 2024 to RMB12.3 billion in 2030, with a CAGR of 122.9%. Claudin 18.2 is observed to highly express in cancers of the digestive system including gastric cancer, esophageal cancer, etc. Based on current clinical trial status in China, the first Claudin 18.2 therapy is estimated to be approved in 2024 for China market based on current clinical trial progress, and the market is projected to be only RMB0.1 billion in the first year of commercialization due to factors such as time needed for market education for new therapy and testing for Claudin 18.2-positive patients who are eligible. Based on the current clinical progress, it is projected to have five to 10 Claudin 18.2-based antibody drugs before 2030. Moreover, with clinical development, more indications covering esophageal cancer, pancreatic cancer, CRC, etc. with Claudin 18.2 high expression will obtain approval gradually. As another innovative oncology therapy, the pricing of Claudin 18.2-based antibody drugs is assumed to be similar with that of PD-1/L1 antibody drugs while facing more competitions. Benchmarking with the growth of PD-1/L1 drugs which reached RMB13.7 billion in the third year of commercialization, the Claudin 18.2-based antibody market is expected not to exceed 10 billion until 2030 when it has a market of RMB12.3 billion, seven years after initial approval and commercialization. The following diagram illustrates the size of China Claudin 18.2-based antibody from 2017 to 2021 and the estimated market size from 2022 to 2030:

Claudin 18.2-based Antibody Market in China, 2017-2030E



Source: Frost & Sullivan Report

Competitive landscape

The current pipeline of Claudin 18.2-targeted therapies in China includes: monoclonal antibody (mAb), bispecific antibody, ADC, fusion protein and CAR-T. The following table sets forth the clinical-stage pipeline of Claudin 18.2-targeted therapies in China as of the Latest Practicable Date:

Drug name/code	Company	Indications	Phase	First posted date	Drug type
BA1105	**Our Group**	**Advanced solid tumors that have failed standard treatment(1)**	**Phase 1**	**2022-02-23**	**mAb**
Zolbetuximab	Astellas	Claudin 18.2-positive, HER2-negative, locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, pancreatic cancer	Phase 3	2019-04-19	mAb
ZL-1211	Zai Biopharmaceutical	Claudin 18.2-positive metastatic or locally advanced solid tumors	Phase 1/2	2022-03-29	mAb
LM-102	LaNova Medicines	Claudin 18.2-positive advanced solid tumors	Phase 1/2	2021-07-22	mAb
ASKB589	Aosaikang	Advanced solid tumors	Phase 1/2	2020-10-29	mAb
AB011	CARsgen Therapeutics	Claudin 18.2-positive solid tumors	Phase 1	2020-05-21	mAb
TST001	MabSpace Biosciences	Solid tumors	Phase 1	2020-08-03	mAb
MIL93	Mabworks Biotech	Locally advanced or metastatic solid tumors	Phase 1	2020-12-02	mAb
M108	FutureGen	Advanced solid tumors	Phase 1	2021-03-31	mAb
IBI360	Innovent	Advanced malignant tumors	Phase 1	2021-08-26	mAb
NBL-015	Xinshi Biopharma	Claudin 18.2-positive advanced solid tumors	Phase 1	2021-12-08	mAb
JS012	Shanghai Junshi Biosciences	Solid tumor	Phase 1	2022-01-10	mAb
BC008	Baochuan	Claudin 18.2-positive advanced solid tumors	Phase 1	2022-06-27	mAb
PM1032	Biotheus	Advanced solid tumors	Phase 1/2a	2022-03-29	Bispecific antibody
TJ033721	I-Mab Biopharma	Advanced solid tumors	Phase 1	2022-03-31	Bispecific antibody
Q-1802	QureBio | CMAB Biopharma	Advanced solid tumors	Phase 1	2021-04-14	Bispecific antibody
QLS31905	Qilu Pharma	Claudin 18.2-positive malignant solid tumors	Phase 1	2021-08-27	Bispecific antibody
IBI389	Innovent	Advanced malignant tumors	Phase 1	2021-12-01	Bispecific antibody
BC007	Baochuan	Claudin 18.2-positive advanced solid tumors	Phase 1	2022-10-31	Bispecific antibody
DR30303	Zhejiang Doer Biologics	Claudin 18.2-positive advanced solid tumors	Phase 1	2022-03-28	Fusion protein
RC118	RemeGen	Claudin 18.2-positive locally advanced unresectable or metastatic malignant solid tumors	Phase 1/2a	2021-11-29	ADC
LM-302	LaNova Medicines	Claudin 18.2-positive advanced solid tumors	Phase 1/2	2021-11-17	ADC
CMG901	Keymed Biosciences	Advanced solid tumors with no standard treatment options	Phase 1	2020-12-09	ADC
SHR-A1904	Hengrui Medicine	Advanced pancreatic cancer; advanced solid tumors	Phase 1	2021-05-17	ADC
SYSA1801	CSPC	Claudin 18.2-positive advanced malignant solid tumors	Phase 1	2021-08-16	ADC
SKB315	Sichuan Kelun Biotech	Claudin 18.2-positive advanced solid tumors	Phase 1	2022-02-14	ADC
JS107	Shanghai Junshi Biosciences	Claudin 18.2-positive advanced solid tumors	Phase 1	2022-05-24	ADC
CT041	CARsgen Therapeutics	Advanced gastric/gastroesophageal junction adenocarcinoma that fails at least second-line treatment, advanced pancreatic cancer that fails at least first-line treatment	Phase 1b/2	2020-10-09	CAR-T

Note:

(1) Based on Company information, indications include advanced gastric cancer, metastatic pancreatic cancer, and adenocarcinoma of the esophagogastric junction.

Source: Frost & Sullivan Report

PD-L1/TGF-β market

PD-L1 expressed on the tumor cells binds to PD-1 receptors on the activated T cells, which leads to the inhibition of the cytotoxic T cells. In the tumor microenvironment, transforming growth factor ß (TGF-ß) is well-known for its immunosuppressive role and serves as a driver of tumor progression by suppressing the host antitumor immune response and by inducing tumor cell plasticity. PD-L1/TGF-ß target therapy aims to target these two molecules.

Since many cancers fail to respond to antibodies targeting immune checkpoints such as PD-L1 due to tumor-induced immune tolerance in the tumor microenvironment, it is important to target molecules in the tumor microenvironment that will drives immune dysfunction to ensure better effectiveness of immune checkpoint inhibitor therapy.

We independently develop BA1201, a product candidate for the treatment of SCLC, NSCLC, cervical cancer, urothelial carcinoma, and advanced gastrointestinal tumors, with PD-L1 and TGF-β targets.

Market size

For the details of PD-1/L1-based antibody market size, see "— Oncology biologics market — Oncology biosimilars market — Nivolumab market — Market size" in this section.

Competitive landscape

The following tables sets forth the clinical-stage PD-L1/TGF-β target therapies in China as of the Latest Practicable Date:

Drug code/name	Company	Target	Indications	Phase	First posted date
BA1201	**Our Group**	**PD-L1, TGF-β**	**SCLC, NSCLC, cervical cancer, urothelial carcinoma, advanced gastrointestinal tumors**	**Phase 1**	**2022-08-30**
M7824	Merck	PD-L1, TGF-β	Solid tumors (including biliary tract cancer, NSCLC and unresectable cervical cancer)	Phase 3	2022-04-21
SHR-1701	Jiangsu Hengrui Medicine	PD-L1, TGF-β2	Advanced CRC, gastric cancer, cervical cancer, non-squamous NSCLC, NSCLC, perioperative treatment for resectable locally advanced gastric or gastroesophageal junction cancer, head and neck squamous cell carcinoma, pancreatic cancer, nasopharyngeal carcinoma, advanced malignant solid tumors, locally advanced rectal cancer	Phase 3	2021-11-17
LBL-015	Leads Biolabs	PD-L1, TGF-β	Advanced solid tumors	Phase 1/2	2021-09-22
BJ-005	BJ Bioscience	PD-L1, TGF-β	Advanced solid tumors	Phase 1+2a	2022-03-09
PM8001	Biotheus	PD-L1, TGF-β	Advanced solid tumors, lung cancer	Phase 1/2a	2020-06-24
BR102	Hisun Biopharma | BioRay Pharmaceutical	PD-L1, TGF-β	Advanced malignant tumors	Phase 1	2021-09-13
Y101D	Wuhan YZY Biopharma	PD-L1, TGF-β	Metastatic or locally advanced solid tumors	Phase 1	2021-07-22
QLS31901	Qilu Pharma	PD-L1, TGF-β	Advanced malignant tumors	Phase 1	2021-06-02
JS201	Shanghai Junshi Biosciences	PD-1, TGF-β2	Advanced malignant tumors	Phase 1	2021-05-21
TQB2858	Jiangsu Chia Tai Tianqing	PD-L1, TGF-β	Alveolar soft part sarcoma, Advanced pancreatic cancer, Advanced malignant tumors, Advanced high-grade sarcoma	Phase 1	2021-03-25
6MW3511	Mabwell Bioscience	PD-L1, TGF-β	Advanced solid tumors	Phase 1	2022-09-01
HB0028	Huabo Biopharm	PD-L1, TGF-β	Advanced solid tumors	Phase 1	2022-08-09
TST005	MabSpace Biological	PD-L1, TGF-β	Advanced solid tumors	Phase 1	2022-07-01
GT90008	Kintor Pharmaceutical	PD-L1, TGF-β	Cholangiocarcinoma	Phase 1	2022-05-31

Source: Frost & Sullivan Report

CEA/CD3 market

CEA/CD3 bispecific antibody is an IgG1-based bispecific heterodimeric antibody that binds with one arm to CD3ε chain expressed on T cells and with two arms to CEA expressed on tumor cells. Upon simultaneous binding to targets, it rapidly crosslinks T cells to tumor cells, leading to the activation of the CD3 downstream signaling pathway and formation of the immunologic synapses.

We independently develop BA1202, a product candidate for the treatment of solid tumors, with CEA and CD3 targets.

Competitive landscape

As of the Latest Practicable Date, there was no marketed CEA-CD3 bispecific antibody for treatment of solid tumors globally and in China. RO6958688, manufactured by Roche, was the only CEA-CD3 bispecific antibody in clinical stage globally as of the same date, the details of which are set forth below. In China, there was no relevant drug candidates in clinical stage as of the same date.

Drug code/name	Company	Target	Drug type	Indication	Phase	First posted date
RO6958688	Roche	CEA-CD3	Bispecific antibody	Metastatic NSCLC	Phase 1b/2	2017-11-09

Source: Frost & Sullivan Report

CD25 market

CD25 (IL2Ra) is a component of IL-2 receptor, which are present in both effector T cells and regulatory T cells. IL-2 receptor is involved in the activation of T cells, which improves T-cell survival, differentiation and proliferation. IL-2 receptor is composed of 3 subunits, IL2Ra (CD25), IL2Rβ (CD122) and IL2γ (CD132).

Upon binding to IL-2 receptor, IL-2 activates PI3K pathway, MAPK pathway and STAT pathways, which are responsible for cell survival, proliferation and differentiation respectively. Upon binding of CD25 antibody on regulatory T cells, IL-2 signaling pathways are blocked so regulatory T cells will be reduced, which in turn, tipping the regulatory T and effector T cell balance towards more effector cells, and enhance effector T cell activity upon tumor cells.

We independently develop BA1106, a product candidate for the treatment of solid tumors, with CD25 target.

Competitive landscape

As of the Latest Practicable Date, there was no marketed CD25 antibody for treatment of solid tumors globally and in China. As of the same date, there were three drug candidates targeting CD25 in clinical stage globally. In China, BA1106 from our Group is the first clinical-staged CD25-targeting antibody indicated for solid tumors. The following table sets forth the clinical-stage CD25 antibody globally and in China as of the Latest Practicable Date:

Region	Drug code/name	Company	Target	Drug type	Indication	Phase	First posted date
China	**BA1106**	**Our Group**	**CD25**	**mAb**	**Solid tumors**	**Phase 1**	**2022-11-21**
Global	AU-007	Aulos Bioscience	CD25	mAb	Advanced solid tumors, unresectable locally advanced or metastatic cancer	Phase 1/2	2022-03-04
Global	RO7296682	Roche	CD25	mAb	Advanced and/or metastatic solid tumors	Phase 1	2019-11-12
Global	ADCT-301	ADC Therapeutics S.A.	CD25	ADC	Advanced solid tumors	Phase 1	2018-08-09

Source: Frost & Sullivan Report

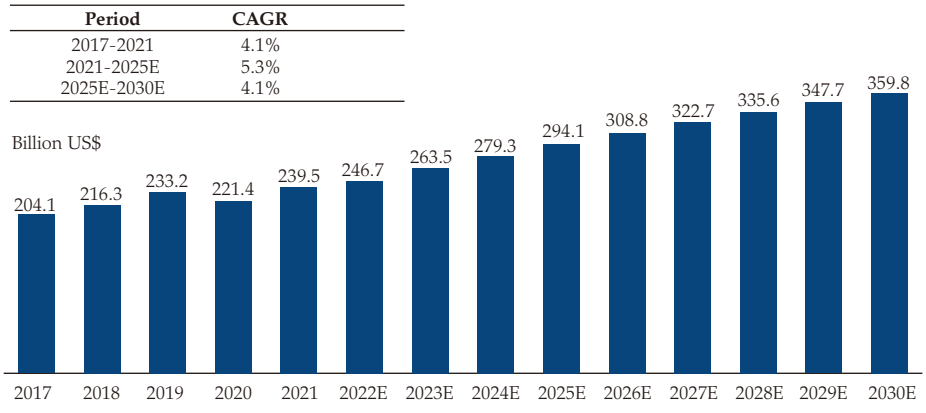
METABOLISM BIOLOGICS MARKET

Osteoporosis is a skeletal disease that is associated with an imbalance in bone resorption and formation, leading to a loss of bone mass and deterioration of bone microarchitecture. Two categories of osteoporosis have been identified including primary and secondary osteoporosis. Primary osteoporosis is the most common form of the disease and includes postmenopausal osteoporosis (type I), and senile osteoporosis (type II). Secondary osteoporosis is characterized as having a clearly definable etiologic mechanism. In postmenopausal women, the decrease in estrogen levels causes bone resorption rates to be greater than bone formation rates. While the disease process of osteoporosis is silent, the loss of bone strength increases the risk of fractures. Osteoporotic fractures typically occur at the hip, distal forearm, spine or proximal humerus, and fractures of the hip and spine are associated with increased morbidity and mortality.

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Type 2 diabetes is a type of diabetes caused by a progressive insulin secretory defect on the background of insulin resistance. The number of type 2 diabetes patients accounts for the vast majority of the global diabetes patients.

The global metabolism drug market increased from US$204.1 billion in 2017 to US$239.5 billion in 2021, with a CAGR of 4.1%, and is expected to increase to US$359.8 billion in 2030 with a CAGR of 4.6% from 2021 to 2030. The global metabolism market was dominated by diabetes drugs with a share of approximately 67.7%. The global top five best-selling metabolism drugs in 2021 by brand name are Trulicity®, Jardiance, Ozempic, Farxiga and Januvia, accounting for 8.5%, 8.0%, 7.0%, 4.3% and 4.3% of the total global metabolism drug market, respectively. The following diagram illustrates the size of global metabolism drug market from 2017 to 2021 and the estimated market size from 2022 to 2030:

Global Metabolism Drug Market Size and Forecast, 2017-2030E

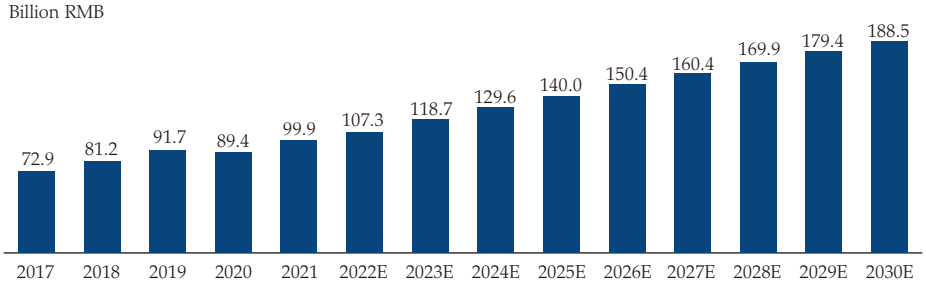


Source: Frost & Sullivan Report

Similarly, the China metabolism drug market increased from RMB72.9 billion in 2017 to RMB99.9 billion in 2021, with a CAGR of 8.2%, and is expected to increase to RMB188.5 billion in 2030, with a CAGR of 7.3% from 2021 to 2030. China metabolism market was dominated by diabetes drugs with a share of approximately 64.8%. China top five best-selling metabolism drugs in 2021 by brand name were Novomix 30, Novolin 30R, Lantus, Chang Xiu Lin and Glucophage, accounting for 8.6%, 7.6%, 6.3%, 4.8% and 4.6% of the total China metabolism drug market, respectively. The following diagram illustrates the size of China metabolism drug market from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Metabolism Drug Market Size and Forecast, 2017-2030E

Period	CAGR
2017-2021	8.2%
2021-2025E	8.8%
2025E-2030E	6.1%



Source: Frost & Sullivan Report

Metabolism biosimilars market

Denosumab market

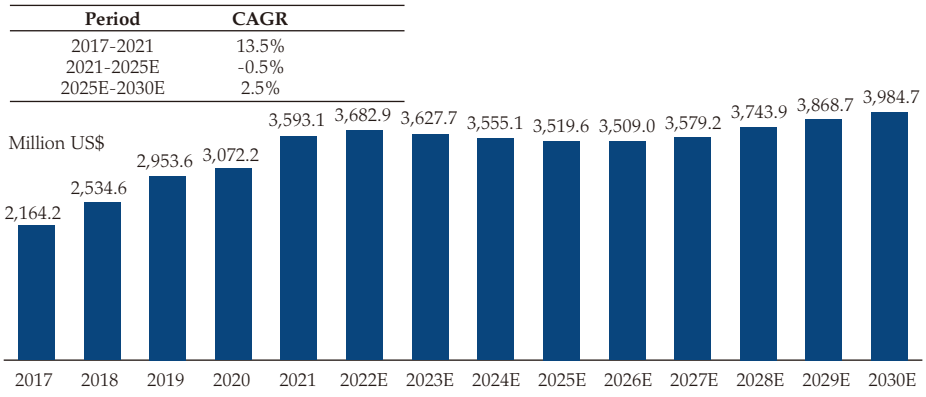
Denosumab is a fully human monoclonal antibody that binds RANKL, preventing RANKL from activating RANK, its receptor on the osteoclast surface. See "— Oncology biologics market — Oncology biosimilars market — Denosumab market" in this section for further details on denosumab.

We independently developed BA6101, a biosimilar to Prolia® (denosumab) targeting postmenopausal women with osteoporosis at high risk for fracture. We received the regulatory approval to commence commercialization of BA6101 in November 2022 in China. It is also currently under Phase 1 clinical trial in the EU.

Market size

According to the Frost & Sullivan Report, the global denosumab market size of Prolia® and its biosimilars increased from US$2,164.2 million in 2017 to US$3,593.1 million in 2021, with a CAGR of 13.5%, and is expected to increase to US$3,984.7 million in 2030, with a CAGR of 1.2% from 2021 to 2030. The following diagram illustrates the global denosumab market size of Prolia® and its biosimilars from 2017 to 2021 and the estimated market size from 2022 to 2030:

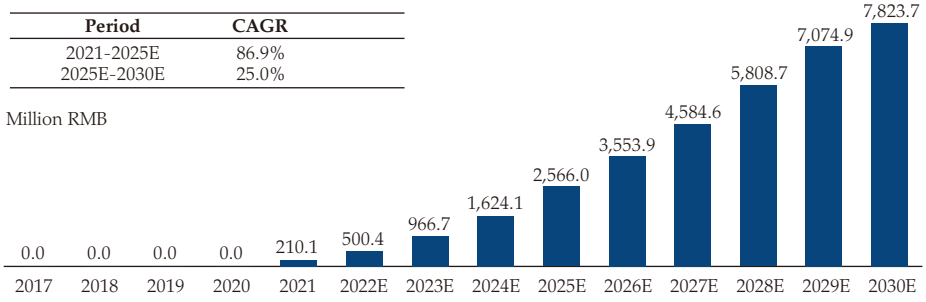
Global Denosumab Market Size and Forecast (Prolia® and its Biosimilars), 2017-2030E



Source: Frost & Sullivan Report

There was no Prolia® (denosumab) biosimilars marketed in China from 2017 to 2020 according to the Frost & Sullivan Report. The sales revenue of denosumab market of Prolia® and its biosimilars in China in 2021 was RMB210.1 million and is expected to increase to RMB7,823.7 million in 2030, with a CAGR of 49.5%. Prolia® has been approved for indication of osteoporosis in China. As approximately 60% of the global sales revenue of Prolia® was generated from the United States, it is reasonable to benchmark the 2030 China market estimation to U.S. clinical practice in 2020, when Prolia® has been used clinically by more than 500 thousand patients, representing a penetration rate of approximately 6.0% in osteoporosis patients. Assuming that China will reach the similar penetration rate in 2030 given the improving affordability by NRDL inclusion and price erosion from biosimilar competition, a total of 8.1 million patients will have the opportunity to use Prolia®, generating a market of RMB7.8 billion in 2030 in China. The following diagram illustrates the China denosumab market size of Prolia® and its biosimilars from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Denosumab Market Size and Forecast (Prolia® and its Biosimilars), 2017-2030E



Source: Frost & Sullivan Report

Competitive landscape

Prolia® (denosumab) has been launched in the United States, the EU and China, the details of which are set forth below. As of the Latest Practicable Date, BA6101 was the only Prolia® (denosumab) biosimilar approved in China.

Brand name	Generic name	Company	Region/authority	Initial approval date	Approved indications	Annual cost per patient	2021 global sales revenue	NRDL
Prolia® 普羅力 (reference drug)	Denosumab	Amgen	U.S./FDA	2010-06-01	• Treatment of postmenopausal women with osteoporosis at high risk for fracture • Treatment to increase bone mass in men with osteoporosis at high risk for fracture • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	~US$2,868.3	US$3.6 Billion	-
		Amgen	EU/EMA	2010-05-26	• Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures • Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures • Treatment of bone loss associated with long-term systemic glucocorticoid therapy in audit patients at increased risk of fracture	NA		-
		Amgen	China/NMPA	2020-06-17	• Treatment of postmenopausal women with osteoporosis at high fracture risk	~RMB1,247.1		Category B(1)
博优倍®		**Our Group**	**China/NMPA**	**2022-11-08**	• **Treatment of postmenopausal women with osteoporosis at high fracture risk**	**NA**	**NA**	**Category B(1)**

Note:

(1) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

(2) NA means public information is not available.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, globally (outside of China), there were 11 clinical-stage Prolia® (denosumab) biosimilar candidates, the details of which are set forth below:

Drug name/code	Company	Region	Phase	Indications	First posted date
BA6101	**Our Group**	**Europe**	**Phase 1**	**Osteoporosis**	**2020-10-20**
GP2411	Sandoz	US, Europe, Japan	Phase 3	Postmenopausal osteoporosis	2019-06-04
SB16	Samsung Bioepis	Poland	Phase 3	Postmenopausal osteoporosis	2020-12-11
TVB-009	Teva Pharmaceuticals	US	Phase 3	Postmenopausal osteoporosis	2021-01-28
CT-P41	Celltrion	Europe	Phase 3	Postmenopausal osteoporosis	2021-02-17
FKS518	Fresenius Kabi SwissBioSim GmbH	Europe	Phase 3	Postmenopausal osteoporosis	2021-06-22
RGB-14-P	Gedeon Richter Plc.	US, Europe	Phase 3	Postmenopausal osteoporosis	2021-10-21
MB09	mAbxience S.A	Europe, Mexico	Phase 3	Postmenopausal osteoporosis	2022-04-20
AVT03	Alvotech Swiss AG	South Africa	Phase 3	Postmenopausal osteoporosis	2022-05-27
ENZ215	Enzene	Czechia	Phase 3	Postmenopausal osteoporosis	2022-06-06
INTP23	Lambda Therapeutics	India	Phase 3	Postmenopausal osteoporosis	2022-06-15

Note:

(1) For overseas biosimilars to enter the China market, data from overseas clinical trials can be accepted for BLA since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018.

Source: Frost & Sullivan Report

Similarly, as of the Latest Practicable Date, there were a number of clinical-stage Prolia® (denosumab) biosimilar candidates in China, the details of which are set forth below:

Drug name/code	Company	Phase	Indications	First posted date
QL1206	Qilu Pharma	BLA	Postmenopausal osteoporosis with high fracture risk	2021-09-06
9MW0311	Jiangsu T-mab Bio-Pharma	BLA	Postmenopausal osteoporosis	2021-12-22
KN012	Suzhou Alphamab | Feiyang Biotech	Phase 3	Postmenopausal osteoporosis with high fracture risk	2020-07-31
CMAB807	Shanghai Biomabs Pharma | Shanghai MabLab Biotech	Phase 3	Postmenopausal osteoporosis with high fracture risk	2020-11-17
HLX14	Henlius Biotech	Phase 3	Postmenopausal osteoporosis with high fracture risk	2022-03-18
MV088	KPC Pharma	Phase 1	Postmenopausal osteoporosis with high fracture risk	2020-11-27
HS-20090-2	Shanghai Hansoh Biomedical	Phase 1	Postmenopausal osteoporosis with high fracture risk	2021-07-16

Source: Frost & Sullivan Report

Major patents for denosumab will expire in the United States in 2025 and in the EU predominantly in 2025. Major patents for denosumab in China have expired in June 2022.

The common first-line treatment of postmenopausal women with osteoporosis at high risk for fracture is bisphosphonates. FDA-approved indications for bisphosphonates include treatment of osteoporosis in postmenopausal women, osteoporosis in men, glucocorticoid-induced osteoporosis, hypercalcemia of malignancy, Paget's disease of the bone, and malignancies with metastasis to the bone. Prolia® is the first and only RANKL inhibitor for osteoporosis in China and is recommended in the "Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis". Multiple studies to date have shown that, RANKL inhibitors can significantly increase the bone mineral density of the lumbar spine, hip and femoral neck and reduce the risk of fracture. Treatment for men with osteoporosis at high risk for fracture, glucocorticoid-induced osteoporosis in men and women at high risk for fracture, as well as treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, are similar to first-line therapy for postmenopausal women with osteoporosis at high risk for fracture, also including bisphosphonates and RANKL inhibitors. Denosumab treatment requires subcutaneous injection, 60 mg every six months, and patients need 1000 mg calcium and 400 IU vitamin D supplementation daily during treatment.

According to "Diagnosis and Management of Osteoporosis" published by American Academy of Family Physicians, the National Osteoporosis Foundation recommends treatment of postmenopausal women and men with a personal history of hip or vertebral fracture, a T-score of -2.5 or less, or a combination of low bone mass (T-score between -1 and -2.5) and a 10-year probability of hip fracture of at least 3% or any major fracture of at least 20% as calculated by the FRAX Fracture Risk Assessment Tool. The WHO recommendations are less specific, stating that persons with or at risk of osteoporosis should be considered for treatment. Treatment for osteoporosis includes non-pharmacologic therapy and pharmacologic therapy. Pharmacologic therapy for osteoporosis mainly includes bisphosphonates, raloxifene (Evista), calcitonin, teriparatide (Forteo), and denosumab (Prolia®). Bisphosphonates are considered first-line pharmacologic therapy.

Dulaglutide market

Type 2 diabetes is the most common type of diabetes, accounting for about 95% of all diabetes cases. It is generally characterized by insulin resistance, where the body does not fully respond to insulin. For some people with type 2 diabetes this can ultimately exhaust the pancreas, resulting in the body producing less and less insulin, causing even higher blood sugar levels. Globally, the number of type 2 diabetes patients rises steadily from 434.6 million in 2017 to 479.0 million in 2021, with a CAGR of 2.5%, and is expected to increase to 585.5 million in 2030 with a CAGR of 2.3% from 2021 to 2030.

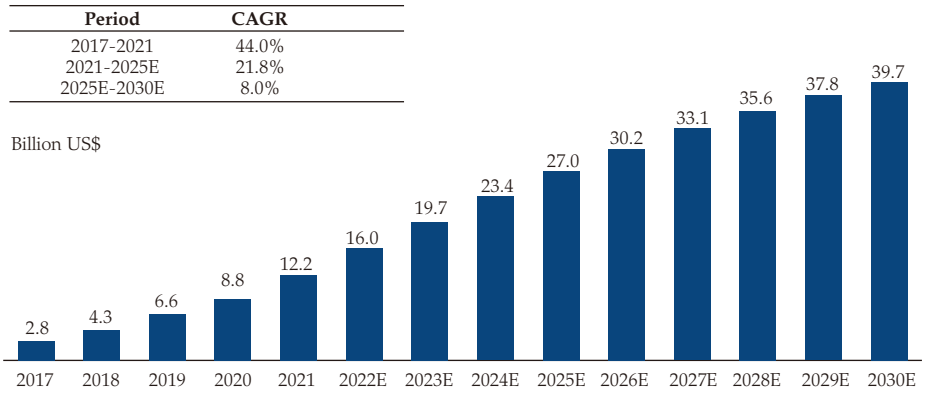
In healthy people, GLP-1 is secreted after eating, reducing glucose concentration by increasing insulin secretion and inhibiting glucagon release. The GLP-1 receptor agonist is a GLP-1 analog with most of the properties of GLP-1 and a longer half-life, and can be used to treat patients with type 2 diabetes whose GLP-1 secretion is impaired. GLP-1 drugs can be divided into short-acting GLP-1 drugs and long-acting GLP-1 drugs. According to 2021 Standards of Medical Care in Diabetes by American Diabetic Association, among patients with type 2 diabetes who have established atherosclerotic cardiovascular disease (ASCVD) or established kidney disease, GLP-1 receptor agonist with demonstrated cardiovascular disease (CVD) benefit is recommended as part of the glucose-lowering regimen. Compared to short-acting GLP-1 drugs, the advantages of long-acting GLP-1 drugs are better glycemic control, better medication compliance and suitable for patients with high susceptibility to gastrointestinal discomfort.

We independently develop BA5101, dulaglutide injection and a biosimilar to Trulicity®, for the treatment of type 2 diabetes, which is one of the long-acting GLP-1 drugs and is under Phase 3 clinical trial in China. Major patents for dulaglutide will expire in December 2027, June 2029, and December 2025 in the United States, the EU and China, respectively.

Market size

According to the Frost & Sullivan Report, the global long-acting GLP-1 drug market increased from US$2.8 billion in 2017 to US$12.2 billion in 2021, with a CAGR of 44.0%, and is expected to increase to US$39.7 billion in 2030, with a CAGR of 14.0% from 2021 to 2030. The following diagram illustrates the size of global long-acting GLP-1 market from 2017 to 2021 and the estimated market size from 2022 to 2030:

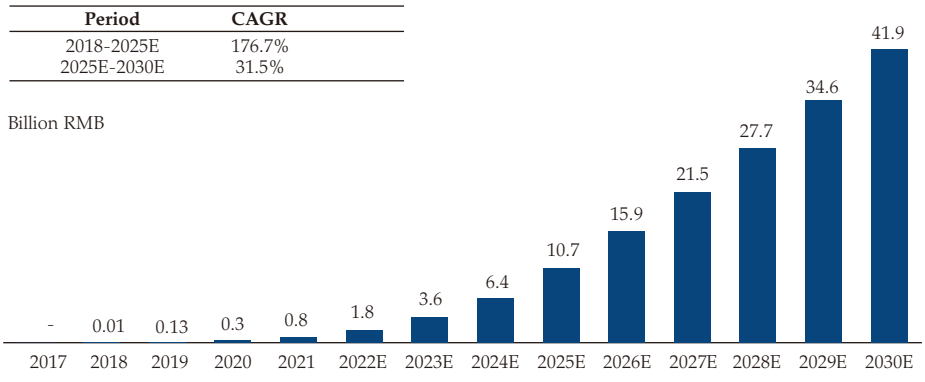
Global Long-acting GLP-1 Drug Market Size and Forecast, 2017-2030E



Source: Frost & Sullivan Report

The sales revenue of China's long-acting GLP-1 market increased from nil in 2017 to RMB0.8 billion in 2021, and is expected to increase to RMB41.9 billion in 2030, with a CAGR of 54.2% from 2021 to 2030. GLP-1 is an innovative class of drug for Type 2 diabetes, demonstrating superior glucose-lowering effect. Moreover, long-acting GLP-1 further brings convenience to and facilitates better medication compliance and adherence for chronic Type 2 diabetes patients who require life-long time medication. Once commercialized, long-acting GLP-1 drugs have demonstrated a fast growth in developed countries. In 2020, it successfully helped more than 600 thousand patients in the treatment of Type 2 diabetes in the United States, representing a penetration rate of approximately 2.0% of U.S. Type 2 diabetes patients. Benchmarked with that, assuming China will have 2.0% Type 2 diabetes patients using long-acting GLP-1 drugs in 2030, China will have a total market of long-acting GLP-1 drugs of RMB41.9 billion as a result. The following diagram illustrates the size of China long-acting GLP-1 drug market from 2017 to 2021 and the estimated market size from 2022 to 2030:

China Long-acting GLP-1 Drug Market Size and Forecast, 2017-2030E



Source: Frost & Sullivan Report

In 2021, the global sales revenue of Trulicity® was the highest among the approved long-acting GLP-1 drug products globally. Since FDA approval of Trulicity® in September 2014, the global sales revenue of Trulicity® rises rapidly from US$248.7 million in 2015 to US$6.6 billion in 2021, with a CAGR of 72.7% during the period.

Competitive landscape

The treatment of type 2 diabetes varies depending on the patient's entry A1C level, which is a measure of blood glucose level. For patients with entry A1C <7.5%, monotherapy is used with metformin being the preferred drug. For patients with entry A1C ≥7.5% – 9.0%, dual therapy involving metformin and another drug is used, and if glycemic control is not reached, triple therapy will be used. For patients with A1C >9.0%, insulin can be added for treatment. Independent of glycemic control, if established ASCVD (atherosclerotic cardiovascular disease) or high risk, CKD 3 (stage 3 chronic kidney disease), or HFrEF (heart failure with reduced ejection fraction), long-acting GLP1 receptor agonist, including dulaglutide, or SGLT2 inhibitor is recommended. Non-insulin glucose-lowering drugs include biguanides (metformin), alpha-glucosidase inhibitors, DPP-4 inhibitors, SGLT2 inhibitors, sulfonylureas, TZDs (thiazolidinediones), and GLP-1 receptor agonists.

As of the Latest Practicable Date, there was no clinical-stage biosimilars of Trulicity® globally (outside of China). In China, there were five clinical-stage biosimilars of Trulicity® as of the same date. The details are set forth below:

Drug name/code	Company	Indication	Phase	First posted date
BA5101	**Our Group**	**Type 2 diabetes**	**Phase 3**	**2022-07-25**
SL209	SL Pharm	Type 2 diabetes	Phase 1	2022-04-26
14028	Dongguan HEC Biopharmaceutical R&D	Type 2 diabetes	Phase 1	2022-04-21
Recombinant GLP-1 receptor agonist	Lepu Medical	Type 2 diabetes	Phase 1(1)	2021-07-28
SAL015	Genekey Biotech | Suzhou Genemen Biotech	Type 2 diabetes	Phase 1(1)	2020-08-31

Note:

(1) Based on CDE information, phase 1 clinical trials of recombinant GLP-1 receptor agonist and SAL015 have been completed.

Source: Frost & Sullivan Report

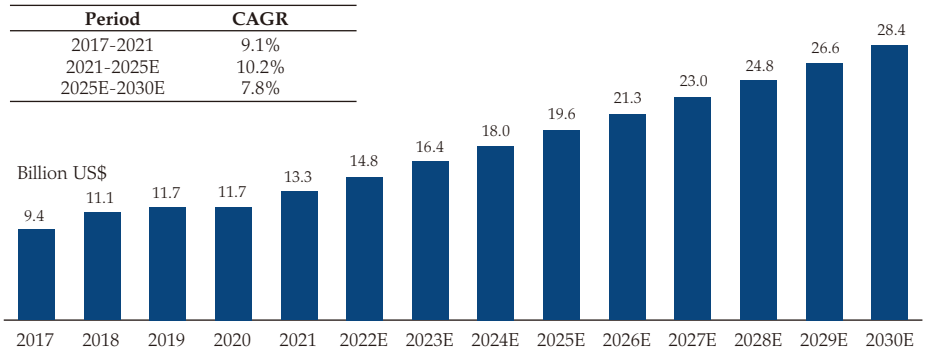
OPHTHALMOLOGY BIOLOGICS MARKET

Retinal diseases, which are often characterized by leakage of fluid, hemorrhage and fibrous scarring in the eye, include wAMD, DME RVO and mCNV. These diseases are major causes of visual impairment and blindness worldwide. Apart from the diseases mentioned above, retinopathy also has a high prevalence in patients with diabetes. The anti-VEGF drug is currently the most important therapy for the treatment of retinal diseases.

Market size

The global market size of anti-VEGF monoclonal antibody for retinal diseases increased from US$9.4 billion in 2017 to US$13.3 billion in 2021, with a CAGR of 9.1%, and is expected to further grow to US$28.4 billion in 2030 with a CAGR of 8.8% from 2021 to 2030. The following diagram illustrates the size of global anti-VEGF monoclonal antibody market from 2017 to 2021 and the estimated market size from 2022 to 2030:

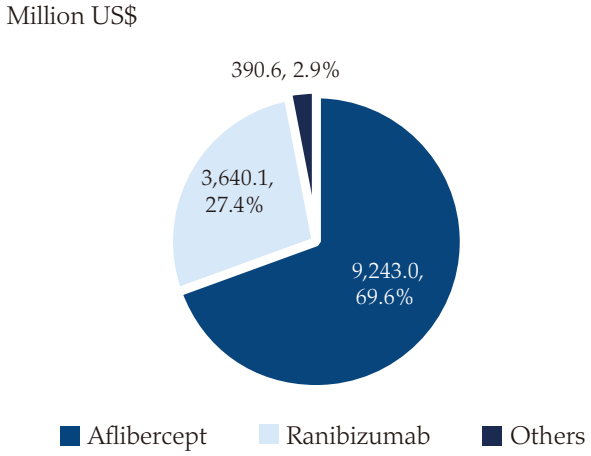
Global Market Size and Forecast of Anti-VEGF Monoclonal Antibody for Retinal Diseases, 2017-2030E



Source: Frost & Sullivan Report

In 2021, there were four anti-VEGF biologics for retinal diseases approved globally, being aflibercept, ranibizumab and others (brolucizumab and conbercept) accounting for 69.6%, 27.4% and 2.9% of the global anti-VEGF biologics market for retinal diseases respectively, in terms of sales revenue.

Breakdown of Global Anti-VEGF Biologics Market for Retinal Disease, 2021



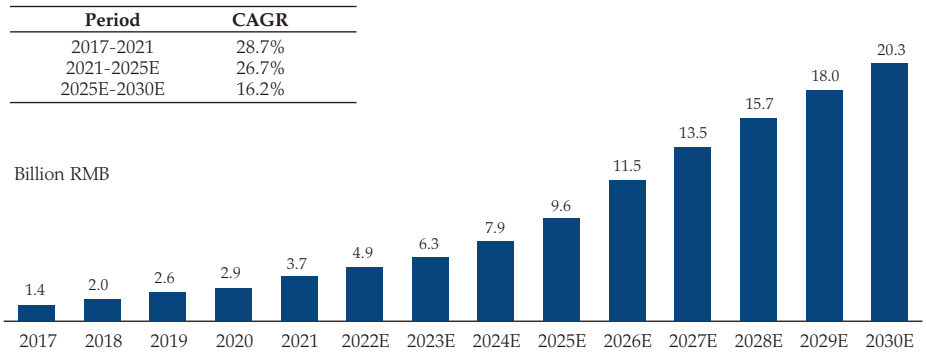
Note:

Others include brolucizumab and conbercept.

Source: Frost & Sullivan Report

The China market size of anti-VEGF monoclonal antibody for retinal diseases increased from RMB1.4 billion in 2017 to RMB3.7 billion in 2021, with a CAGR of 28.7%, and is expected to further grow to RMB20.3 billion in 2030 with a CAGR of 20.7% from 2021 to 2030. The following diagram illustrates the size of China anti-VEGF monoclonal antibody for retinal diseases market from 2017 to 2021 and the estimated market size from 2022 to 2030:

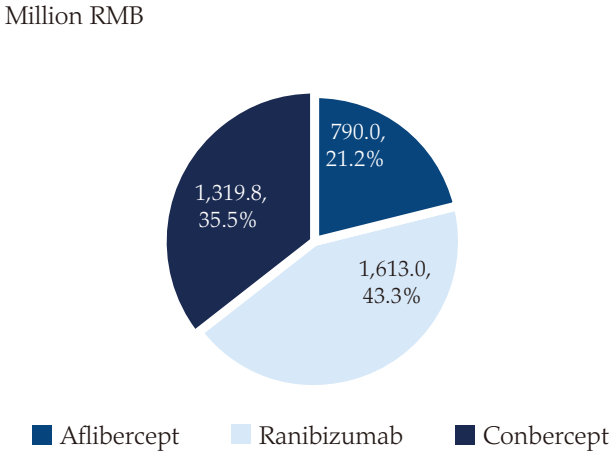
China Market Size and Forecast of Anti-VEGF Monoclonal Antibody for Retinal Diseases, 2017-2030E



Source: Frost & Sullivan Report

In 2021, there were three anti-VEGF biologics for retinal diseases approved in China, being ranibizumab, conbercept and aflibercept accounting for 43.3%, 35.5% and 21.2% of China anti-VEGF biologics market for retinal diseases respectively, in terms of sales revenue.

Breakdown of China Anti-VEGF Biologics Market for Retinal Disease, 2021



Source: Frost & Sullivan Report

Ophthalmology biosimilars market

Aflibercept market

Eylea®, an aflibercept solution for injection into the eye, has been proved to have an advantage in the treatment of DME comparing with macular laser photocoagulation treatment method. Experiment supported its efficacy by a positive outcome from the Phase 3 VISTA-DME clinical trials: after one year, the mean changes in best-corrected visual acuity were significantly improved compared with the control group. Eylea® is indicated for the treatment of patients with wAMD, RVO, DME, and DR.

Our BA9101, a biosimilar to Eylea®, is currently under Phase 3 clinical trial in China.

Market size

In 2021, the global sales of Eylea® amounted to US$9.2 billion, which was the highest among the approved anti-VEGF monoclonal antibodies for retinal diseases globally. In China, the sales revenue of Eylea® amounted to RMB790.0 million in 2021. See "— Ophthalmology biologics market — Market size" in this section for further details of the market size of anti-VEGF monoclonal antibody for retinal diseases.

Competitive landscape

Eylea® has been launched in the United States, the EU and China, the details of which are set forth below. As of the Latest Practicable Date, there was no biosimilar to aflibercept that had launched in any market.

Brand name	Company	Approval time	Indication	Annual cost per patient	2021 global sales revenue	NRDL
Eylea®	Bayer	2018-02 (China/NMPA) 2014-07 (U.S./FDA) 2014-08 (EU/EMA)	DME	~RMB36,900 (China) ~US$16,650 (U.S.) ~€6,536 (EU)	US$ 9,243.0 million	Eylea® is included in Category B(1)
		2018-05 (China/NMPA) 2011-11 (U.S./FDA) 2012-11 (EU/EMA)	wAMD	~RMB32,800 (China) ~US$14,800 (U.S.) ~€5,810 (EU)		
		2019-05 (U.S./FDA)	DR	~US$16,650 (U.S.)		–
		2014-10 (U.S./FDA) 2015-01 (EU)	RVO	~US$24,050 (U.S.) ~€9,441 (EU)		–
		2015-09 (EU)	mCNV	~€8,715 (EU)		–

Note:

(1) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were nine clinical-stage aflibercept biosimilars globally (outside China), further details of which are set forth below:

Region	Drug name/code	Company	Indication	Phase	First posted date
Global	MYL-1701P	Mylan Pharmaceuticals	DME	Phase 3	2018-08-01
Slovakia	CT-P42	Celltrion	DME	Phase 3	2021-02-04
Global	ABP-938	Amgen	wAMD	Phase 3	2020-02-17
Global	SB15	Samsung Bioepis	wAMD	Phase 3	2020-06-29
Global	SCD411	Sam Chun Dang Pharm	wAMD	Phase 3	2020-07-21
Global	FYB203	Bioeq GmbH	wAMD	Phase 3	2020-08-21
Global	SOK583A1	Sandoz	wAMD	Phase 3	2021-04-29
NA	AVT06	Alvotech Swiss AG	wAMD	Phase 3	2021-12-13
Korea	ALT-L9	Alteogen	wAMD	Phase 1	2019-08-15

Notes:

(1) NA means region of clinical trial is not publicly available.

(2) Global means clinical trials are carried out in multiple regions of the world.

(3) For overseas biosimilars to enter the China market, data from overseas clinical trials can be accepted for BLA since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were four clinical-stage aflibercept biosimilars in China, further details of which are set forth below:

Region	Drug name/code	Company	Indication	Phase	First posted date
China/NMPA	**BA9101**	**Our Group**	**wAMD**	**Phase 3**	**2020-11-03**
	QL1207	Qilu Pharma	wAMD	BLA	2022-04-28
			DME	Phase 1	2018-12-07
	9MW0813	Jiangsu Trnab BioPharma | Mabwell | Shanghai Destiny Biotech	DME	Phase 3	2021-10-18
	JZB05	Jingze Pharma	DME	Phase 1	2022-06-21

Source: Frost & Sullivan Report

Major patents for aflibercept will expire in the United States in 2023 and in the EU in 2025. Major patents for aflibercept in China have expired in 2020.

The dosage and administration of aflibercept vary by indication such as the following examples. The treatment is mentioned in the official website for Eylea®: https://hcp.eylea.us/resources/. Anti-VEGF drugs are also mentioned as first-line treatment in preferred practice pattern guidelines published by American Academy of Ophthalmology.

wAMD: Aflibercept is widely used in wAMD. At present, anti-VEGF therapy has become the first-line therapy for wAMD recommended by guidelines of various countries. The recommended dose of aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the first 12 weeks and then once every eight weeks.

DME: As a first-line therapy for DME, the recommended dose of aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the initial five injections, followed by 2 mg (0.05 mL) via intravitreal injection once every eight weeks.

RVO: As a first-line therapy for RVO, the recommended dose for aflibercept is 2 mg (0.05 mL) administered by intravitreal injection once every four weeks.

DR: As a first-line therapy for DR, the recommended dose for aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the first five injections followed by 2 mg (0.05 mL) via intravitreal injection once every eight weeks.

We set forth below a summary of the treatment paradigm of aflibercept for each indication:

wAMD: According to "Age-related Macular Degeneration Preferred Practice Pattern" published by American Academy of Ophthalmology, management options for AMD include observation and early detection, antioxidant vitamin and mineral supplements, intravitreal injection of anti-VEGF agents, photodynamic therapy (PDT), laser photocoagulation surgery, and the encouragement of smoking cessation for patients who currently smoke. Intravitreal injection therapy using anti-VEGF agents (e.g., aflibercept and ranibizumab) is the most effective way to manage wAMD and represents the first line of treatment.

DME: According to "Diabetic Retinopathy Preferred Practice Pattern" published by American Academy of Ophthalmology, management options for DR includes following a healthy diet and lifestyle, medical management, timely ophthalmic evaluation, and treatment under the care of an ophthalmologist. Cost-effective treatments with laser, anti-VEGF agents, or intravitreal corticosteroids may also be considered. Intravitreal anti-VEGF agents are effective in the treatment of center-involved DME with vision loss. Laser photocoagulation surgery remains the preferred treatment for non-center-involved DME and pan-retinal photocoagulation (PRP) surgery remains the mainstay treatment for proliferative diabetic retinopathy (PDR).

RVO: According to "Retinal Vein Occlusions Preferred Practice Pattern" published by American Academy of Ophthalmology, macular edema may complicate both central retinal vein occlusions ("**CRVOs**") and branch vein occlusions ("**BRVOs**"). RVO is classified into CRVOs and BRVOs. The first line of treatment for associated macular edema is anti-VEGF agents. Intravitreal corticosteroids, with the associated risk of glaucoma and cataract formation, have demonstrated efficacy. Also, laser photocoagulation surgery in BRVO has a potential role in treatment. For patients who develop iris neovascularization or retinal neovascularization following a CRVO, peripheral pan-retinal photocoagulation (PRP) treatment is advised. Anti-VEGF agents can be used in an adjunctive manner if angiogenesis continues after PRP.

AUTOIMMUNE INNOVATIVE DRUG MARKET

IL4R market

Interleukin 4 Receptor (IL-4R), also known as CD124, IL4-Rα and BSF receptor, is a type I cytokine receptor produced by activated Th2 cells and mast cells, and plays an important role in Th2-biased immune responses, alternative macrophage activation, mucosal immunity, allergic inflammation, tumor progression, and atherogenesis.

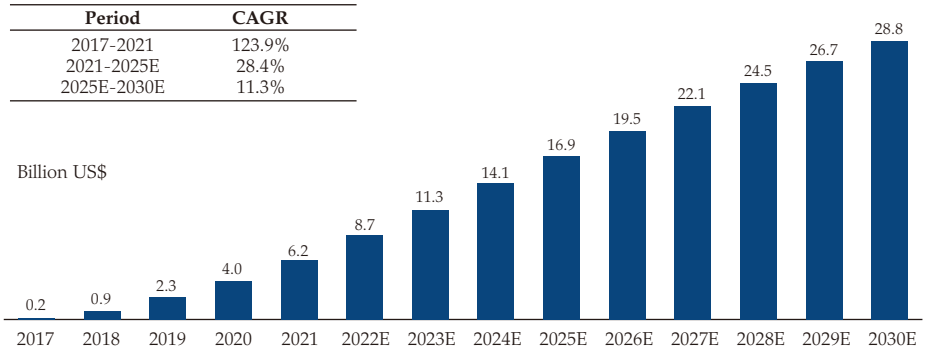
So far, there has been several efficient monoclonal antibodies indicated for severe asthma treatment, the types of which include anti IL-4Rα, anti-IgE, anti-IL-5 and anti-IL-5Rα. According to study revealed statistical analysis, anti-IL-4Rα inhibitor has a superior efficacy, in terms of both reducing risk of exacerbation and improving FEV1, than anti-IL-5, anti-IL-5Rα and anti-IgE inhibitors.

We independently develop BA2101 for the treatment of atopic dermatitis, asthma, sinusitis, pruritus and urticaria with IL4R target.

Market size

The first IL-4Rα drug, Dupixent, was approved in 2017, and its market significantly grew from US$0.2 billion to US$6.2 billion in 2021, with a CAGR of 123.9%. Due to the extrapolation of indications and same target drugs to be approved in future, the market is estimated to reach US$28.8 billion in 2030, representing a CAGR of 18.6% from 2021 to 2030. The following diagram illustrates the size of global IL-4Rα target therapy market from 2017 to 2021 and the estimated market size from 2022 to 2030:

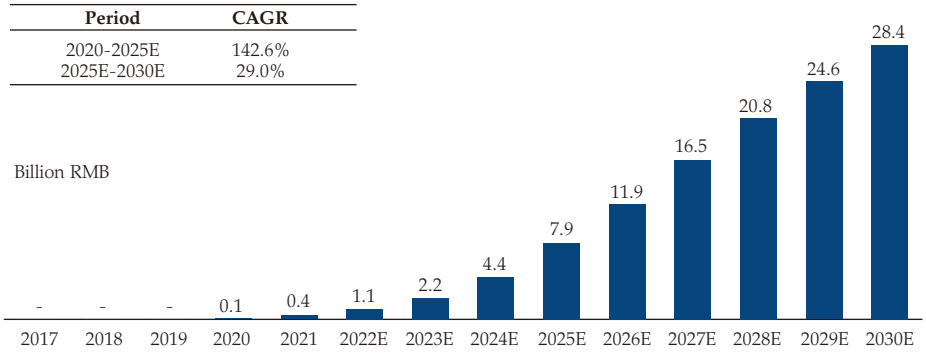
Global IL-4Rα Target Therapy Market, 2017-2030E



Source: Frost & Sullivan Report

With the first IL-4Rα drug, Dupixent, approved by the NMPA in 2020 and included in the NRDL (2020 edition), and the continuous launch of innovative drugs and extrapolation of indications, the market will be fast growing. The IL-4Rα market is projected to reach RMB28.4 billion in 2030, with a CAGR of 58.6% from 2021 to 2030. The following diagram illustrates the size of China IL-4Rα target therapy market from 2017 to 2021 and the estimated market size from 2022 to 2030:

IL-4Rα Target Therapy Market in China, 2020-2030E



Source:Frost & Sullivan Report

Competitive landscape

As of the Latest Practicable Date, dupilumab by Sanofi was the only IL-4Rα target therapy approved by the NMPA. The current pipeline of IL-4Rα target therapies in China includes monoclonal antibody (mAb) only. The following table sets forth the details of dupilumab and all IL-4Rα target therapies in the clinical stage in China as of the Latest Practicable Date.

Drug name/code	Company	Indications	Status	NMPA approval/ first posted date	Drug type
BA2101	**Our Group**	**Atopic dermatitis, asthma, sinusitis, pruritus, urticaria, etc**	**Phase 1**	**2022-10[1]**	**mAb**
Dupilumab	Sanofi	Moderate-to-severe atopic dermatitis	Marketed	2020-06-17	mAb
CM310	Keymed Bioscience	Chronic sinusitis with nasal polyps, moderate-to-severe atopic dermatitis, moderate-to-severe asthma	Phase 3	2022-02-28	mAb
CBP-201	Connect Biopharma	Moderate-to-severe atopic dermatitis, chronic sinusitis with nasal polyps, moderate-to-severe persistent asthma with type 2 inflammation	Phase 2	2020-11-20	mAb
QX005N	Quan Xin Biomedical	Atopic dermatitis	Phase 2	2022-07-14	mAb
SSGJ-611	CP Guojian Pharma	Moderate-to-severe atopic dermatitis	Phase 2	2022-08-24	mAb
MG-K10	Baochuan Biological Medicine Technology | Shanghai Maiji Biotechnology	Moderate-to-severe atopic dermatitis, asthma	Phase 2	2022-07-19	mAb
SHR-1819	Hengrui Medicine	Moderate-to-severe atopic dermatitis, asthma	Phase 2	2022-09-27	mAb
GR1802	Genrixbio	Moderate-to-severe atopic dermatitis, asthma	Phase 1b/2	2021-10-09	mAb
AK120	Akeso	Moderate-to-severe atopic dermatitis	Phase 1b/2	2021-10-22	mAb
TQH2722	Jiangsu Chia Tai Tianqing	Atopic dermatitis	Phase 1	2022-05-17	mAb
LQ036	Shanghai Novamab	Asthma	Phase 1	2022-11-17	mAb

Note:

(1) BA2101 was granted IND approval to commence the phase 1 clinical trial in China in October 2022.

Source: Frost & Sullivan Report

MARKET OF COVID-19 NEUTRALIZING ANTIBODIES

Coronaviruses are a large family of viruses which may cause illness in animals or humans. They are one of the pathogens that causes respiratory tract infection in human. Coronavirus are RNA virus. COVID-19 is caused by a coronavirus called SARS-CoV-2. By far there is no specific treatment that has been recommended for this emerging coronavirus infection except for meticulous supportive care. Neutralizing antibody is one of the most promising therapies for the treatment of COVID-19.

We independently develop LY-CovMab, a fully human monoclonal antibody manufactured by recombinant technology and used to counteract COVID-19, is currently under Phase 2 clinical trial in China. In addition, we are developing BA-CovMab, a fully human monoclonal antibody manufactured by recombinant technology and used to counteract COVID-19, which is currently under Phase 1 clinical trial in China.

Market size

According to the Frost & Sullivan Report, the global COVID-19 neutralizing antibody market was US$1,057.2 million in 2020. In 2021, the combined global sales revenue of COVID-19 neutralizing antibodies exceeded US$9.5 billion. According to WHO, as of the Latest Practicable Date, the total global cumulative case number of COVID-19 was over 600 million. Taking into account the mass vaccination campaigns that were underway in many countries, the estimated market size for COVID-19 neutralizing antibody will likely decrease in the future. However, such estimate remains subject to changes due to factors such as virus mutations and treatment breakthroughs. Given the unpredictable nature of COVID-19 and the aforementioned factors, future market size is unable to be forecasted with certainty.

Competitive landscape for COVID-19 drugs

Due to the high demand for COVID-19 neutralizing antibodies after approval, pharmaceutical companies also seek collaborations to ensure adequate manufacturing and distribution. As of the Latest Practicable Date, there was a total of six COVID-19 neutralizing antibodies that were authorized for use under Emergency Use Authorization ("**EUA**") in the U.S. and/or approved by the EMA in Europe and over 60 clinical-stage COVID-19 neutralizing antibodies being developed globally. The following table illustrates the competitive landscape of COVID-19 neutralizing antibodies that were authorized for use under the EUA in the U.S. and/or approved by the EMA in Europe as of the Latest Practicable Date:

Drug name/code	Company	Status	Indication	Approval date	Authority	Drug type	Cost per treatment cycle (US$)	2021 sales revenue (million US$)
Regdanvimab (Regkirona)	Celltrion	Marketed	COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021 -11 -12	EMA	mAb	NA	37.6 (2021 H1)
REGEN-COV (Ronapreve)	Roche | Regeneron	Marketed	COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021 -11 -12	EMA	Combination of 2 mAbs	2,000	5,828
Sotrovimab (Xevudy)	GSK | Vir	Marketed	COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021-12-17	EMA	mAb	NA	1,317
Evusheld	AstraZeneca	EUA	Pre-exposure prophylaxis for prevention of COVID-19	2021 -12 -08	FDA	Combination of 2 mAbs	NA	85
		Marketed	Prevention of COVID-19 in adults and adolescents from 12 years of age weighing at least 40 kg before potential exposure	2022 -03 -24	EMA			
Tocilizumab (Actemra)	Genentech	EUA	Hospitalized adult and pediatric (two years of age and older) COVID-19 patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation	2021 -06 -24	FDA	mAb	3,159.4	NA
		Marketed	Severe COVID-19 in adults receiving systemic corticosteroids and supplemental oxygen or mechanical ventilation	2021 -12 -07	EMA	mAb		
Bebtelovimab	Eli Lilly	EUA	Mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19 and without alternative treatment options	2022 -02 -11	FDA	mAb	NA	NA

Note:

(1) NA means unavailable public information or due to the fact that some drugs such as tocilizumab are previously approved for other indications and specific sales revenue for use in COVID-19 treatment cannot be separated.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were one marketed and nine clinical-stage COVID-19 neutralizing antibodies in China, the details of which are set forth below:

Drug name/code	Company	Status	Indication	NMPA approval/ First posted date	Drug type	Annual cost per patient (RMB)	2021 China sales revenue (million RMB)
Amubarvimab/ Romlusevimab (BRII-196/BRII-198)[1]	Brii Biosciences	Marketed	Adult and pediatric ((12-17 years of age weighing at least 40 kg) COVID-19 patients with mild or moderate symptoms and a high risk of progressing to severe COVID-19	2021-12-08	Combination therapy of 2 mAbs	NA	NA
Meplazumab	Jiangsu Pacific Meinuoke Bio Pharmaceutical	Phase 2/3	COVID-19	2021-11-09	mAb	NA	NA
SCTA01	Sinocelltech	Phase 2/3	Severe COVID-19	2020-11-25	mAb	NA	NA
BDB-001	Staidson (Beijing) Biopharmaceuticals	Phase 2/3	Severe COVID-19	2020-06-29	mAb	NA	NA
LY-CovMab	**Our Group**	**Phase 2**	**COVID-19**	**2021-08[2]**	**mAb**	**NA**	**NA**
Etesevimab JS016	Shanghai Junshi Bioscience	Phase 2	COVID-19	2021-06-18	mAb	NA	NA
MW33	Mabwell (Shanghai) Bioscience	Phase 2	Mild or moderate COVID-19	2020-11-13	mAb	NA	NA
IBI314	Innovent Biologics	Phase 1/2	Mild or moderate COVID-19	2021-12-29	mAb	NA	NA
HFB30132A	HiFiBiO Therapeutics	Phase 1	COVID-19	2022-03-11	mAb	NA	NA
BA-CovMab	**Our Group**	**Phase 1**	**COVID-19**	**2022-09[3]**	**mAb**	**NA**	**NA**

Notes:

(1) Based on the company's announcement and the Chinese patent search, the relevant patent for BRII-196/BRII-198 is expected to expire in 2041 in China.

(2) LY-CovMab was granted approval to commence the Phase 2 clinical trial in China in August 2021.

(3) BA-CovMab was granted approval to commence the Phase 1 clinical trial in China in September 2022.

Source: Frost & Sullivan Report

The following table sets forth the treatment paradigm of COVID-19:

Patient group	Drug category	Recommended regimen	Dosage	Cost per treatment cycle (US$)
Non-severe COVID-19	Chemical drug	• Remdesivir (Veklury)	One dose daily for three consecutive days as intravenous infusion as 200 mg intravenously on day 1, followed by 100 mg intravenously on days 2 and 3.	2,080 (US)/ 1,560 (outside of the US)
		• Nirmatrelvir-ritonavir (Paxlovid)	300 mg (two 150 mg tablets) of nirmatrelvir end 100 mg of ritonavir every 12 hours daily for 5 days	530
		• Molnupiravir (Lagevrio)	800 mg tablet every 12 hours daily for five days	700
Severe COVID-19	Chemical drug	• Remdesivir (Veklury)	200 mg intravenously on day 1, followed by 100 mg intravenously on days 2-10	5,720 (US)/ 4,290 (outside of the US)
	Chemical drug + mAb + polypeptide	• Baricitinib (Olumiant) + IL-6 receptor blocker (tocilizumab) + corticosteroids	N/A	N/A
	mAb + polypeptide	• IL-6 receptor blocker (tocilizumab) + corticosteroids	N/A	N/A
	Polypeptide	• Systemic corticosteroids	N/A	N/A
Critical COVID-19	Chemical drug + mAb + polypeptide	• Baricitinib (Olumiant) + IL-6 receptor blocker (tocilizumab) + corticosteroids	N/A	N/A
	mAb + polypeptide	• IL-6 receptor blocker (tocilizumab) + corticosteroids	N/A	N/A
	Polypeptide	• Systemic corticosteroids	N/A	N/A

Notes:

(1) This table only includes COVID-19 drugs that are authorized for use under the EUA by FDA and/or approved by EMA in Europe as of the Latest Practicable Date.

(2) Non-severe disease means absence of signs of severe or critical disease.

(3) Severe disease means oxygen saturation of <90% on room air, signs of pneumonia and signs of severe respiratory distress.

(4) Critical disease means the patient requires life sustaining treatment, acute respiratory distress syndrome, sepsis, and septic shock.

Source: Frost & Sullivan Report

SOURCE OF INFORMATION

In connection with the [**REDACTED**], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the global and China biologics markets. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries.

We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of biologics markets for potential investors. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan also adopted the following primary assumptions while making projections on the macroeconomic environment, the overall pharmaceutical market and various segment markets in the PRC for the forecast period: the overall social, economic and political environment in the PRC remains stable; China's economic and industrial development remains stable; key industry drivers, such as accelerated population aging, growing demands from healthcare institutions, increasing prevalence of chronic diseases and technology innovation continue to drive the growth of China's pharmaceutical market; and no extreme force majeure or industry regulation will dramatically or fundamentally affect the market. Frost & Sullivan believes that these assumptions are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

We have agreed to pay Frost & Sullivan a fee of RMB1,210,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [**REDACTED**]. We confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan which may qualify, contradict or have an impact on the information set forth in this section in any material respect.

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business.

REGULATORY AUTHORITIES

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration (國家藥品監督管理局) (the "**NMPA**"), the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the "**NHC**") and the National Healthcare Security Administration (國家醫療保障局) (the "**NHSA**").

The NMPA, the successor of the China Food and Drug Administration (the "**CFDA**"), the State Food and Drug Administration (the "**SFDA**") and the State Drug Administration (the "**SDA**"), is an authority under the State Administration for Market Regulation (國家市場監督管理總局) (the "**SAMR**") and is the primary regulator for medical products. It is primarily responsible for the supervising and managing drugs, medical devices and cosmetics, including drafting of relevant regulations and policies; undertaking standard management, registration regulation, quality management and postmarket risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics; undertaking management of qualifications for licensed pharmacists.

The NHC is primary national regulator for public health. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

The NHSA is an authority directly under the State Council responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

LAWS AND REGULATIONS IN RELATION TO DRUG MANUFACTURER

Drug Manufacturing Permit

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") in September 1984 and lastly amended in August 2019 and came into effect in December 2019, the state adopts an industry entry permit system for drug manufacturers. The establishment of a drug manufacturer shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people's government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

Good Manufacturing Practices

Prior to December 1, 2019, establishment of a new drug manufacturer, construction of new production premise for a drug manufacturer or production of new dosage form are required to submit application for good manufacturing practice certification (GMP certification) with the drug regulatory authority in accordance with relevant provisions. If the Good Manufacturing Practices are satisfied, a GMP certificate will be issued. Pursuant to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Good Manufacturing Practices (《藥品生產質量管理規範》), promulgated by the Ministry of Health of the PRC (the "**MOH**", now known as the NHC) in March 1988, newly amended in January 2011 and came into effect in March 2011, provided guidance for the quality management, organization and staffing, production premises and facilities, equipments, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a manufacturer in a systematical manner.

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

Application for New Drug Registration

Drug registration refers to an approval process where the NMPA conducts review of the safety, efficacy and quality controllability of the drugs intended for marketing according to the application for drug registration made by an applicant, and decides whether to approve the application. Drug registration applications include new drug application, generic drug application, imported drug registration application and supplementary application, as well as re-registration application. Pursuant to the provisions of the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》(2020)), promulgated by the SAMR in January 2020 and came into effect in July 2020, the Measures for the Administration of Drug Registration shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. In accordance with the Measures for the Administration of Drug Registration, drugs registration refers to activities that a drug registration applicant files an application and other supplementary applications for clinical drug trial, approval for drug marketing, and re-registration, among others, under the legal procedures and according to the relevant requirements, and that the medical products administrative department examines the safety, effectiveness, and quality controllability based on the laws and regulations, and the existing scientific cognitions, to decide whether to agree with the activities applied for. A drug registration certificate shall be valid for five years. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

Non-clinical Research and Animal Testing

The non-clinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the SFDA in August 2003 and latest amended by CFDA in July 2017 and came into effect on September 1, 2017. The SFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) in April 2007, which specifies the requirements for institutions applying for Good Laboratory Practice (GLP) certification of non-clinical laboratory studies.

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission in November 1988 and lastly amended in March 2017 by the State Council, the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities in December 2001 and came into effect in January 2002, performing conservation, breeding, production, supply, transportation and related commercial operations of experimental animals and related products requires a Certificate for

Production of Laboratory Animals. A Certificate for Production of Laboratory Animals shall be valid for five years, and the holder shall apply for renewal six months prior to the expiry of the validity period.

Application for Clinical Trial

After completing the pre-clinical studies, the applicant must obtain approval for clinical trials of drugs (including bioequivalence tests) from the NMPA before the conduction of new clinical drug trials. According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017 and came into effect on May 1, 2017, the decision on the approval of clinical trials of drugs enacted by the CFDA can be made by the Center for Drug Evaluation (the "**CDE**") from May 1, 2017. Pursuant to the Drug Administration Law, the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data and the samples, shall, in accordance with the regulations of the drug regulatory authority under the State Council be truthfully submitted to the said department for approval before clinical drug trial is conducted. The drug regulatory authority of under State Council shall decide whether to approve the clinical trial application and notify the decision to the clinical trial applicant within 60 business days from the date of accepting the clinical trial application. If the drug regulatory authority under the State Council fails to do so, the clinical trail application shall be deemed as approval, and if the bioequivalence test is conducted, it is required to report it to the drug regulatory authority under State Council for filing. Neither the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) nor the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) provides that conducting clinical trials at different Phases requires individual or additional approvals by the CDE.

Before conducting the clinical trial, the applicant shall file a series of detailed documents with the NMPA, and send a copy to the competent provincial drug administration department. According to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013, all clinical trials approved by the CFDA and conducted in the PRC shall complete the clinical trial registration and information disclosure on the Drug Clinical Trial Information Platform. The applicant must complete the initial registration of the trial within one month after obtaining the approval of the clinical trial to obtain the unique registration number of the trial; and complete the subsequent data registration before the first patient is enrolled and submit it for the first time for disclosure.

After obtaining clinical trial approval, the applicant shall choose institutions qualified for clinical trials of the drug to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is

responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

Clinical Trial (Five Phases)

In compliance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), clinical trials are divided into Phase 1, Phase 2, Phase 3, Phase 4 and bioequivalence trial:

A clinical drug trial to be carried out shall be examined and approved by the ethics committee. The management of drugs used in a clinical drug trial shall satisfy the relevant requirements of the GCP. A sponsor approved to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the CDE.

Clinical trials shall be conducted for the application of new drug registration and shall be implemented in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), promulgated by the NMPA and NHC and came into effect on July 1, 2020. The Good Clinical Practice for Drug Trials stipulates the criteria for the entire procedure of the clinical trial including pre-clinical trial preparation and the necessary conditions, protection of testees' rights and interests, trial protocols, duties of researchers, duties of sponsors, duties of monitors, trial record and report, data management and statistical analysis, administration of drug products for trial, guarantee for quality, polycentric trials, with reference to the internationally recognized principles. The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) and the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) do not require that Phase 3 clinical trials may be conducted only after Phase 1 or Phase 1b clinical trials are completed.

According to the Announcement of the National Medical Products Administration on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》), if a new drug clinical trial has been approved to be carried out, after the completion of Phase 1 and Phase 2 clinical trials and before the implementation of Phase 3 clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues including the design of the phase 3 clinical trial design. The applicant can also apply for communication on key technical issues at different stages of clinical research and development.

New Drug Application

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), after completing the pharmaceutical research, pharmacological and toxicological research, clinical drug trial, and other researches supporting the marketing

registration of a drug, determining the quality standards, completing the verification of commercial large-scale production process, and making sound preparation for the acceptance of drug registration inspection and examination, an applicant shall file an application for drug marketing authorization, and submit relevant research materials in accordance with the requirements of the application materials. After the formal examination of the application materials, an application that satisfies the requirements shall be accepted. Where a generic drug, *in vitro* diagnostic reagent managed as a drug, or any other eligible circumstance assessed by an applicant to be unnecessary or impossible for conducting clinical drug trial and meeting the conditions for exempting clinical drug trial, the applicant may directly file an application for drug marketing authorization. The technical guiding principles and relevant specific requirements for exempting clinical drug trial shall be developed and announced by the CDE.

The CDE shall organize pharmaceutical, medical and other technical personnel to evaluate the accepted applications for drug marketing authorization as required. Where the comprehensive evaluation conclusion is adopted, the drug shall be approved for marketing, and a drug registration certificate shall be issued. If the comprehensive evaluation conclusion is not adopted, a disapproval decision shall be made. A drug registration certificate shall specify the drug approval number, holder, manufacturer and other information. An over-the-counter (OTC) drug registration certificate shall also indicate the type of OTC drug.

Drug registration inspection means the inspection activities carried out for the development sites and production sites for verifying the authenticity and consistency of the application materials and the commercial production conditions for marketing of drugs, and examining the compliance of drug development, and data reliability, among others, and the extended examination activities carried out for manufacturers, suppliers, or other entrusted institutions of chemical active pharmaceutical ingredients ("**APIs**"), auxiliary materials, and packaging materials and containers in direct contact with drugs involved in the application for drug registration, if necessary.

The CDE shall decide whether to carry out on-site inspection of drug registration development based on risks, according to the degree of drug innovation and the previous acceptance of inspection by drug research institutions.

The CDE shall decide whether to launch production site inspection for drug registration based on risks according to the factors such as variety, process, facility, and previous acceptance of inspection for which an application is filed for registration. For innovative drugs, new modified drugs and biological products, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted. For generic drugs, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted based on the risks, according to whether a drug production license for the corresponding production scope has been obtained and whether a variety of the same dosage form has been marketed.

After an application for drug registration is accepted, the CDE shall conduct preliminary examination within 40 days of acceptance, notify the CDE of organizing inspection and provide the relevant materials required for inspection, where production site inspection for drug registration is required, and concurrently notify the applicant and the medical products administrative department of the province, autonomous region, or municipality in the place where the applicant or production enterprise is located. In principle, the Center for Inspection shall complete the inspection work 40 days prior to the expiry of the time limit for inspection, and report the inspection information, inspection results and other relevant materials to the CDE.

Drug registration examination shall include standard review and sample examination. Standard review means the laboratory assessment of the scientificity of the items set in the standards for the drug for which the applicant applies, the feasibility of the test methods, and the rationality of quality control indicators, among others. Sample examination means the laboratory examination carried out for samples according to the application of the applicant or the drug quality standards verified by the CDE.

The review period for an application for drug marketing authorization shall be 200 working days. Within this 200 working days period, the review period for the procedures for prioritized review and approval shall be 130 working days, and the review period for the procedures for prioritized review and approval for clinically and urgently needed overseas-marketed drug for a rare disease shall be 70 working days.

The following duration shall be excluded from the relevant work period: (i) time taken for the applicant to provide supplementary materials, to make correction upon examination as well as to verify manufacturing process, quality standards and literature in accordance with the requirements; (ii) delay in examination or inspection due to reason of the applicant, time taken for organizing expert advisory meetings; (iii) the suspended duration in the event of suspension of review and approval procedures pursuant to the provisions of laws and regulations; and (iv) time taken for overseas examination where such overseas examination is activated.

Reform of Evaluation and Approval System for Drugs

In August 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (《關於改革藥品醫療器械審評審批制度的意見》) (the "**Reform Opinions**"), which provides a framework for reforming the evaluation and approval system for drugs and indicates enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

In November 2015, the CFDA promulgated the Announcement on Certain Policies for Drug Registration, Evaluation and Approval (《關於藥品註冊審評審批若干政策的公告》) (the "**Certain Policies Announcement**"), which further clarifies the measures and policies on simplifying and accelerating the approval process on the basis of the Reform Opinions.

Pursuant to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA in March 2017 and came into effect in May 2017, the clinical trial approval decisions on drugs (including domestic and imported) can be directly made by the CDE in the name of the CFDA; decisions on approval of drug supplementary applications (including domestic and imported); decisions on approval of re-registration of imported drugs.

The Evaluation and Approval Procedures for Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》), the Evaluation and Approval Procedures for Conditionally Approved Drugs (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》) and The Preferential Evaluation and Approval Procedures for Drug Marketing Authorization (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) promulgated by the NMPA in July 2020 and came into effect in July 2020, replace the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) promulgated by the CFDA in December 2017 and came into effect in December 2017, which further clarified the Accelerating Registration Procedures for Drugs.

Regulations of Biosimilars

According to the Biosimilar Guidelines, biosimilars refer to therapeutic biological products that are similar to approved and registered reference drugs in terms of quality, safety and efficacy. The R&D and marketing of biosimilars need to comply with the relevant regulations of the PRC Drug Administration Law (《中華人民共和國藥品管理法》) and the Administrative Measures for Drug Registration (《藥品註冊管理辦法》). After completion of pre-clinical studies, the applicant is required to propose an application for a clinical trial, and after receiving the approval to conduct a clinical trial, the applicant should complete the clinical trial in accordance with the clinical trial protocol. The applicant shall submit an application for a marketing authorization after completion of the clinical trials and related preparations. For details, see "— Laws and regulations in relation to new drug — Application for new drug registration" and others which set forth in the this section.

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), drug registration shall be subject to registration and administration by categories, namely Chinese medicine, chemical medicine and biological products etc. Biological product registration shall be categorized in accordance with biological product innovative medicine, biological product improved new medicine, marketed biological products (including biosimilar), etc. In order to cooperate with the implementation of the Administrative Measures for Drug Registration, the NMPA formulated the Registration Classification of Biological Products and Requirements for Application Materials (《生物製品註冊分類及申報資料要求》), and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Materials part

came into effect on October 1, 2020. According to the Registration Classification of Biological Products and Requirements for Application Materials, the biosimilars are classified as category 3.3.

According to the CFDA's Circular on the Release of the Technical Guidelines for R&D and Evaluation of Biosimilars (《國家食品藥品監督管理總局關於發佈〈生物類似藥研發與評價技術指導原則〉的通告》) on 28 February 2015, biosimilars shall be filed under the application procedures for new drugs. Application materials for therapeutic biological products shall be submitted following specific requirements in the Biosimilar Guidelines. According to Guidelines on the Acceptance and Review for Registration of Therapeutic Biological Products (Trial) (《治療用生物製品註冊受理審查指南(試行)》). In general, therapeutic biological products under Categories 13 to 15 shall conduct Phase 3 clinical trial only and may submit plans for Phase 3 clinical trial and relevant clinical application materials.

In February 2015, the CFDA released the Biosimilar Guidelines, which outline the regulatory framework for biosimilars in China and provide the basic principles for the evaluation and management of biosimilars. It sets forth the definition of biosimilars and reference drugs, the requirements in relation to the selection of reference drugs, the basic principles for the technical review, the criteria for comparability, and the conditions under which extrapolations of indications would be permissible. According to the Biosimilar Guidelines, R&D of biosimilar drugs are based on contrast experimental studies to prove their similarities with reference drugs, supporting their safety, efficacy and quality control, a biosimilar drug should in principle have the same amino acid sequence as the reference drug, and the R&D and evaluation of biosimilars should be carried out in accordance with basic principles (i.e. comparison principle, dose-escalation principle, consistency principle and equivalence principle) and should cover pharmaceutical, non-clinical and clinical research and evaluation. For PK contrast experimental studies, equivalence design is usually used to study similarities of absorption/bioavailability. Equivalence thresholds should be set in advance and their reasonableness should be demonstrated, and elimination characteristics (e.g. clearance rate, elimination half-lives) should be analyzed.

The Biosimilar Guidelines set out provisions for the expansion of indications of biosimilars. When similarities are proved in comparative trials, the indications of biosimilars may be expanded to include other indications of reference drugs. The expanded indications shall be those with same pathological mechanisms and/or receptors and the same action mechanisms and targets. In comparative trials, appropriate indications shall be selected and subsequent evaluation shall be made on the safety and immunogenicity of the expanded indications. The expansion of indications shall be considered according to product features on case basis. However, caution shall be taken in expanding indications for groups with combined medication, patients with different combined diseases and different recommended dosage.

On February 10, 2021, the NMPA issued the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) to further standardize the development and evaluation of biosimilars, which came into effect on the same day. According to the Technical Guidelines for

similarity evaluation and indication extrapolation of Biosimilars, "similarity" refers to a drug candidate that is overall similar to a reference drug that is approved for registration and that does not present clinically meaningful differences in quality, safety, and efficacy, and "Indication Extrapolation" refers to a drug candidate that is overall similar to the reference drug when directly aligned to clinical trials showing that the candidate is clinically similar to the reference drug in at least one indication. It may then be possible to extrapolate scientific arguments for indication related study data and information in support of its use for other indications not directly studied as approved in China for the reference drug. The similarity evaluation of biosimilars should be carried out comprehensively from the perspective of pharmaceutical, non-clinical and clinical studies to determine the overall similarity, and should be carried out at different stages of biopharmaceutical studies.

The Technical Guidance for Clinical Pharmacology Studies of Biosimilars(《生物類似藥臨床藥理學研究技術指導原則》)issued by the CDE in February 2022 provides further guidance recommendations for clinical pharmacology studies of biosimilars in the framework of The Biosimilar Guidelines and the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars, in which it is clear whether the candidate and reference drugs have similarity in clinical pharmacology needs to be evaluated based on statistical methods; currently, the average bioequivalence statistical approach is generally recommended for the comparison of PK and PD parameters.

With respect to the application and approval process for imported biosimilars developed overseas, according to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), the importation of biosimilars which have been approved overseas shall be examined by the drug regulatory authority of the State Council. Import approval shall be granted only after the examination confirms that the drugs comply with quality standards and are safe for use. A Registration Certificate for Imported Drugs shall then be issued. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), the application for registration of drugs produced overseas shall be filed in accordance with the requirements for the detailed classification and the corresponding application materials.

See "Summary" and "Business" for the details of our biosimilar portfolio.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law, the state implements the drug marketing authorization holder system for drug management. After obtaining a drug registration certificate, an applicant shall be the drug marketing authorization holder. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

The drug marketing authorization holder shall proactively carry out post-marketing research on drugs, further confirm the safety, effectiveness and quality controllability of drugs, and strengthen the continuous management of marketed drugs. Where a drug registration certificate and its annex require the marketing authorization holder to carry out relevant research work after the drug is marketed, the marketing authorization holder shall complete the research within the prescribed time limit and file a supplementary application, undergo recordation formalities or report as required. After a drug is approved for marketing, the marketing authorization holder shall continue to conduct research on drug safety and effectiveness, undergo recordation formalities in a timely manner or file a supplementary application for revising the instructions according to the relevant data, and continuously update and improve the instructions and labels. According to the duties, the medical products administrative department may require the marketing authorization holder to revise the instructions and labels based on the monitoring of adverse drug reactions and the post-marketing reevaluation results of the drug.

The marketing authorization holder shall apply for re-registration six months prior to the expiry of the validity period of the drug registration certificate. An application for re-registration of a domestically produced drug shall be filed by the marketing authorization holder with the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government, and an application for re-registration of a drug produced overseas shall be filed by the marketing authorization holder with the Center for Drug Evaluation.

Transfer of Drug Marketing Authorisation

Pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), upon approval by the drug administrative department of the State Council, a drug marketing authorisation holder may transfer its drug marketing authorisation. The transferee shall possess the quality management, risk control and liability compensation competence to ensure drug safety, effectiveness and quality controllability, and perform the obligations of the drug marketing permit holder.

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), transfer of drug marketing authorisation by the holder shall declare by way of supplementary application, and implement upon approval.

Pursuant to the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (《藥品上市後變更管理辦法(試行)》), drug post-marketing changes shall not have any adverse impact on the safety, effectiveness and quality controllability of drugs. In the case of an application for the change to a drug holder, the production site, prescription, production techniques and quality standards of the drugs shall be consistent with those of the original drugs. In the case of any change, after the change of the holder has been approved, the holder after the change shall conduct full study, evaluation and necessary verification and shall implement or report such changes upon approval or filing as required.

In the case of an application for the change of a holder of domestically manufactured drugs, the transferee shall, after obtaining the drug manufacturing permit for the corresponding production scope, submit a supplementary application to the CDE. In particular, in the case of an application for the change of a holder of narcotic drugs or psychotropic drugs, the transferee shall also meet the requirements for the quantity and layout of the designated manufacturers of narcotic drugs and psychotropic drugs as determined by the NMPA.

The CDE shall make a decision on whether to approve the change within the prescribed time limit. If the change is approved, the CDE shall issue a supplementary drug application notice with the drug approval number and the valid period of the certificate remains unchanged. The CDE shall also send a copy thereof to the provincial drug regulatory authority at the place where the transferor, the transferee and the manufacturer are located.

The holder after the change shall have a production quality management system that meets the requirements specified in the GMP, undertake the obligations for the management of the drug in the whole life cycle, complete the continuous research work of the drug, ensure that the existing technical requirements are met after the drug is manufactured and marketed, and emphasis the situation of the transferred drug in its initial annual report.

The transferred drug may be sold on the market after passing the inspection for compliance with the GMP and fulfilling the product release requirements.

The provincial drug regulatory authority at the place where the transferee is located shall focus on strengthening the supervision and inspection of the transferred drugs and timely incorporate such supervision and inspection into the daily supervision plan.

Gathering, Collection and Filing of Human Genetic Resources

The Ministry of Science and Technology and the MOH promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) in June 1998. The Interim Measures for the Management of Human Genetic Resources set out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, foreign investment sponsors who gather and collect human genetic resources through clinical trials should file a record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017 and came into effect in December 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the listing of drugs in China.

Pursuant to the Regulations on the Management of Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China's ability to guarantee biosafety and improvement of the level of people's health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations.

On October 17, 2020, SCNPC promulgated Biosecurity Law of the PRC (《中華人民共和國生物安全法》), taking effect from April 15, 2021. This Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbe laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. As per this Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of China, upon obtaining the approval or record-filing; the establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law; (i) collecting human genetic resources of important genetic families or specific areas in China, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent department of science and technology under the State Council, (ii) preserving China's human genetic resources, (iii) using China's human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China's human genetic resource materials out of the country shall subject to approval of the competent department of science and technology.

The Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (Exposure Draft)（《人類遺傳資源管理條例實施細則(徵求意見稿)》） for public comments on March 21, 2022. The aforementioned exposure draft has refined the Administrative Regulations on Human Genetic Resources of the People's Republic of China, including but not limited to refining the definition of "human genetic resources information", improving the identification standard of "foreign entities", adjusting the scope of application of collection licensing, adjusting and improving the approval procedures for international cooperative scientific research and administrative supervision rules. As of the Latest Practicable Date, it has no legal effect.

Good Clinical Practice Certification and Compliance with the Good Clinical Practice (GCP)

To improve the quality of clinical trials, the NMPA and NHC promulgated the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the "**GCP**") in April 2020 and came into effect on July 1, 2020, which aims to ensure that the clinical trials of drugs are standardized and the results are scientific and reliable, protecting the rights and safety of human subjects. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) promulgated by the general offices of the Chinese Communist Party Central Committee and the State Council in October 2017, the qualification of clinical trial institutions shall be subject to record management. Clinical trials should follow GCP and protocols approved by the ethics committee of each research center. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by the NMPA and NHC and came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is responsible for setting up a filing management information platform for drug clinical trial institution for registration and filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

OTHER LAWS AND REGULATIONS IN RELATION TO MEDICAL INDUSTRY

Laws and Regulations in relation to Basic Medical Insurance

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Programme (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) promulgated by the National Development and Reform Commission (the "**NDRC**"), the SDA and other authorities, came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to the Guiding Opinions on the Pilot of Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點的指導意見》) promulgated by the State Council on July 10, 2007, urban residents (not urban employees) in the pilot areas can voluntarily participate in the basic medical insurance for urban residents. Pursuant to the Opinions of the State Council on the Integration of the Basic Medical Insurance System for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》)

promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents' medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee's basic medical insurance.

Medical Insurance Catalogue

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. A pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in the Pharmacopoeia of the PRC (current edition) (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. Medical Insurance Catalogue are divided into Category A and Category B. Category A is uniformly formulated by the state and shall not be adjusted in various places. Category B is formulated by the state, and each autonomous region or municipality may make appropriate adjustments based on local economic levels, medical needs and medication habits. The sum of the increased and decreased varieties shall not exceed 15% of the total number of Category B medicines formulated by the state. Expenses incurred by the participant using medicines included in Category A shall be paid in accordance with the provisions of the basic medical insurance. Expenses incurred by the participant using medicines included in Category B shall be paid by the participant as to a certain percentage first, and then paid in accordance with the provisions of the basic medical insurance. Therefore, Category B medicines in the Medical Insurance Catalogue in various provinces in the PRC may differ from region to region, and as the specific reimbursement ratio for Category B medicines is formulated by local authorities, inconsistency also exist in the specific proportion of individual outlays. After several adjustments, the currently effective one is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2021) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2021年)》) adjusted by the NHSA and the Ministry of Human Resources and Social Security in 2021 and came into effective since January 1, 2022.

Drug Price

Pursuant to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council's pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發推進藥品價格改革意見的通知》) jointly promulgated by NDRC, NHC, the Ministry of Human Resources and Social Security, Ministry of Industry

and Information Technology, the Ministry of Finance, the MOFCOM and the CFDA on May 4, 2015. From June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be cancelled.

Regulations on Centralized Procurement

In order to deepen the reform of the medical and healthcare system and improve the mechanism for setting drug prices, the State carried out to organize drug centralized procurement.

First, the State launched the trials for the centralized volume-based drug procurement in 11 cities in November 2018. On November 15, 2018, the Joint Procurement Office published the Papers on Drug Centralized Procurement in "4+7 Cities" (《4+7城市藥品集中採購文件》), which launched the national pilot scheme for centralized volume-based drug procurement in the public medical institutions. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an (the "**4+7 Cities**"). On January 1, 2019, the General Office of the State Council also published the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides the detailed measures in the implementation of the national pilot scheme for centralized volume-based drug procurement in the 4+7 Cities.

Second, on the basis of the centralized volume-based drug procurement implemented by 4+7 cities, the State organizes relevant regions to form an alliance to carry out the centralized volume-based drug procurement of cross-regional alliances in September 2019. The Document for Centralized Drug Procurement in the Alliance area (GY-YD2019-1) (《聯盟地區藥品集中採購文件(GY-YD2019-1)》) was issued by the Joint Procurement Office on September 1, 2019. The alliance area includes the provinces and autonomous regions of Shanxi, Inner Mongolia, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Hainan, Sichuan, Guizhou, Yunnan, Xizang, Shaanxi, Gansu, Qinghai, Ningxia and Xinjiang (including Xinjiang Production and Construction Army Unit), except the 4+7 cities in the alliance area.

Third, the State promoted the centralized volume-based drug procurement nationwide in December 2019. According to the Implementing Opinions on Expanding the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect on September 25, 2019, together with the Documents on National Centralized Drug Procurement (GY-YD2019-2) (《全國藥品集中採購文件(GY-YD2019-2)》) issued by the Joint Procurement Office on December 29, 2019 to launch the second batch of state-organized centralized volume-based drug procurement, the model of centralized procurement with target quantity in the pilot program for conducting centralized procurement and use of drugs by the State will be promoted nationwide and all manufacturers of drugs within the scope of centralized procurement marketed in Mainland China, with the approval of the medical products administration, may participate in the pilot program.

The NHSA, the NHC, the NMPA, the Ministry of Industry and Information Technology (the "**MIIT**") and the Logistics Support Department of the Central Military Commission promulgated the Notice on the Commencement of the Second Batch of State Organized Centralized Drug Procurement and Use (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) on January 13, 2020 which became effective on the same date. The second batch of national organization of centralized procurement and use of drugs will no longer be carried out in selected areas but nationwide, and this Notice expands the range of drugs to be centrally procured and used by state organizations, focusing on the selection of more competitive varieties. Considering the clinical efficacy, adverse reactions, the stability of the drug batches and other factors, the specific selection indicators shall be determined by the joint procurement office. In order to comprehensively deepen the reform and establish a standardized and normalized mode of centralized volume-based drug procurement and use, the Joint Procurement Office issued the Documents on National Centralized Drug Procurement (GY-YD2020-1) (《全國藥品集中採購文件(GY-YD2020-1)》) on July 29, 2020 and launched the third batch of State organizations for the centralized volume-based drug procurement.

On January 15, 2021, the Joint Procurement Office issued the Documents on National Centralized Drug Procurement (GY-YD2021-1) (《全國藥品集中採購文件(GY-YD2021-1)》), pursuant to which, the fourth batch of State organizations for the centralized volume-based drug procurement was launched on February 3, 2021.

Drug Technology Transfer

Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer as the transferee and the application for drug registration by the drug manufacturer as the transferee pursuant to the provisions under Technology Transfer Regulations. On August 19, 2009, the SFDA promulgated the Administrative Regulations for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》), to standardise the registration process of drug technology transfer, which includes application for, evaluation, review, approval and supervision of drug technology transfer registration. According to the above regulations, drug technology transfer includes new drug technology transfer and drug production technology transfer. An application for drug technology transfer must be submitted to the provincial drug regulatory authority, and the SFDA will ultimately make an approval decision based on the comprehensive opinions of the drug review center. Eligible applications will receive a letter of approval and a drug approval number for the supplementary application.

Advertising of Pharmaceutical Products and Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which promulgated by SAMR and came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents. Holders of registration certificates or filing certificates of drugs, medical devices, health food and

formula food for special medical purposes as well as the production enterprises and operating enterprises authorized by such holders of certificates shall be applicants for advertising (the "**applicants**"). Applicants may entrust agents to apply for the review of advertisements for drugs, medical devices, health food and formula food for special medical purposes. Applicants may submit their applications at the acceptance windows of advertisement review authorities, or may submit their applications for advertisements for drugs, medical devices, health food and formula food for special medical purposes via letters, faxes, e-mails or e-government platforms. The advertisement review authorities shall review the materials submitted by the applicant and shall complete the review within ten working days from the date of acceptance. After review, for that advertisements that are in line with laws, administrative regulations and these Measures, approval decisions of review shall be made and advertisement approval numbers shall be issued. The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which promulgated by SFDA and came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SFDA. A drug insert sheet should include the important scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindications, precautions, storage, production date, batch number, expiry date, approval number and drug manufacturer. Pursuant to the Measures for The Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards. If no national or professional standards are available, the enterprise can formulate its standards and put into implementation after obtaining the approval of the food and drug administration or bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its packaging standard. Drugs that without packing standards must not be sold or traded (except for drugs for the military).

Drug Distribution and Two-Invoice System

According to the Implementing Opinions on Promoting the "Two-Invoice System" for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)》) which was issued on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off basis. Wholly-owned or holding commerce companies (there shall be only one commerce company throughout the

country) and domestic general agents of overseas drugs (there shall be only one domestic general agent throughout the country) that are established by drug manufacturers or group enterprises integrating scientific research, manufacture, and trade to sell the drugs of these enterprise (groups) can be regarded as manufacturers. Within an enterprise that is a drug circulation group, the allocation of drugs between the group and wholly-owned (holding) subsidiaries or between wholly-owned (holding) subsidiaries should not be regarded as invoicing, but invoicing is allowed once at most.

According to the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017, on a priority basis, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) and pilot cities for public hospital reform, with the goal of having it implemented nationwide by 2018. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

LAWS AND REGULATIONS IN RELATION TO ADMINISTRATION OF PATHOGENIC MICROORGANISM LABORATORIES

According to the Regulations on the Bio-safety Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全管理條例》) promulgated by State Council and latest amended in March 2018, the pathogenic microorganism laboratories are classified into Level 1, Level 2, Level 3 and Level 4 in accordance with its biosafety level for pathogenic microorganisms and the national standards for the bio-safety. Laboratories at Bio-safety Level 1 and Level 2 are forbidden to conduct experimental activities relating to any highly pathogenic microbes. Laboratories at Bio-safety Level 3 and Level 4 shall meet certain requirements to conduct experimental activities relating to any highly pathogenic microbes. Newly building, rebuilding or expanding of Bio-safety Level 1 or Level 2 laboratories shall file with the relevant health administrative department or veterinary administrative department in the municipal people's government of the place where it is built. The laboratories of Bio-safety Level 3 and Level 4 shall be subject to the state accreditation for laboratories. Laboratories passing accreditation will be granted with Certificates for Bio-safety Laboratories at corresponding level. The certificate will be effective for five years.

REGULATIONS IN RELATION TO INTELLECTUAL PROPERTY

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》) (the "**Patent Law**"), which was promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 and came into effect on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) (the "**Implementation Rules**"), promulgated by the State Council on June 15, 2001 and latest amended on January 9, 2010 and came into effect on February 1, 2010. The Patent Law and the Implementation Rules provide for three types of patents, namely "invention," "utility model" and "design." "Invention" refers to any new technical

solution relating to a product, a process or improvement thereof; "utility model" refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and "design" refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for "invention" is 20 years, and the duration of a patent right for "utility model" or "design" is 10 years, from the date of application. According to the Patent Law, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaty participated by the PRC.

The newly amended Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the Patent Administration Department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed 14 years. Such newly adopted patent term extension rule benefits the Company through providing longer protection terms of patents applied or registered in the PRC and related to our product candidates. This rule needs to be further elaborated by the competent authority, and the benefits we could enjoy are subject to the relevant clarifications and explanations.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the PRC (《中華人民共和國商標法》), which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, and the Implementation Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which were promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014 and came into effect on May 1, 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of 10 years to registered trademarks. When it is necessary to continue using the registered trademark upon expiration of period of validity, a trademark registrant shall make an application for renewal within 12 months before the expiration in accordance with the requirements. If such an application cannot be filed within that period, an extension period of six months may be granted. The period of validity for each renewal of registration shall be 10 years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the MIIT, on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

REGULATIONS IN RELATION TO FOREIGN DIRECT INVESTMENT

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**") promulgated by the National People's Congress (the "**NPC**") has come into effect. The Law of the PRC on Sino-Foreign Equity Joint Ventures and the Law of the PRC on Wholly Foreign-Owned and Law of the PRC on Sino-Foreign Cooperative Joint Ventures abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favourable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2021 Revision) (《外商投資准入特別管理措施(負面清單)(2021年版)》) issued by the NDRC and the MOFCOM on December 27, 2021, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements. While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, the MOFCOM is responsible for coordinating and guiding the reporting of foreign investment information nationwide. The competent commercial department of the local people's government at or above the county level, as well as the relevant agencies of the Pilot Free Trade Zone and the National Economic and Technological Development Zone, are responsible for reporting information on foreign investment in the region. Foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to

the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancellation reports, and annual reports. Foreign investors who establish foreign invested enterprises in China or acquire domestic non-foreign-invested enterprises through equity merger and acquisition shall submit initial reports through the enterprise registration system when applying for the registration of the establishment of foreign-invested enterprises or applying for the registration of the change of the acquired enterprises. If the change in the information of initial reports involves registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system when applying for the registration or filing of change of enterprises. If the change in the information of initial reports does not involve registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system within 20 working days after the change. Foreign-invested listed companies may report information on changes in investors and their shareholdings only when the cumulative change in the foreign investors' shareholding ratio exceeds 5% or the foreign parties' shareholding or relative holding status have changed.

REGULATIONS IN RELATION TO PRODUCT LIABILITY

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the SCNPC on February 22, 1993 and latest amended on December 29, 2018 (the "**Product Quality Law**"), is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable to compensate for any bodily injuries or damage to property other than the defective product itself resulting from the defects in the product, unless the manufacturer is able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall be liable to compensate for any bodily injuries or damage to property of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate neither the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and latest amended on October 25, 2013 and came into effect on March 15, 2014 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. All business operators must pay high attention to protecting customers' privacy and must strictly keep confidential any consumer information they obtain during their business operations.

REGULATIONS IN RELATION TO PRODUCTION SAFETY

The Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC on June 29, 2002 and latest amended on June 10, 2021 and came into effect on September 1, 2021, is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the above requirements may not engage in production and business operation activities. The production and business operation entities shall educate and train employees regarding production safety so as to ensure that the employees have the necessary knowledge of production safety, are familiar with the relevant regulations and rules for safe production and the rules for safe operation, master the skills of safe operation in their own positions, understand the emergency measures, and know their own rights and duties in terms of production safety. Employees who fail the education and training programmes on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project (the "**construction project**") shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the construction project.

REGULATIONS IN RELATION TO ENVIRONMENTAL PROTECTION

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the SCNPC on December 26, 1989 and latest amended on April 24, 2014 and came into effect on January 1, 2015, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002 and latest amended on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 and latest amended on July 16, 2017 and came into effect on October 1, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

According to the Administrative Measures on Pollutant Emission Permits (Trial) (《排污許可管理辦法(試行)》), promulgated by the Ministry of Environmental Protection on January 10, 2018 and latest amended on August 22, 2019, enterprises, institutions and other producers and operators (the "**pollutant discharge enterprises**") that have been included in the Classification Management List for Fixed Source Pollution Permits shall apply for and obtain a discharge permit in accordance with the prescribed time limit. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

REGULATIONS IN RELATION TO PREVENTION AND CONTROL OF OCCUPATIONAL DISEASES

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the "**Prevention and Control of Occupational Diseases Law**"), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

REGULATIONS IN RELATION TO IMPORT AND EXPORT OF GOODS

According to the Provisions of the PRC on the Administration of Recordation of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》), promulgated by the General Administration of Customs of the PRC on November 19, 2021, which came into effect on January 1, 2022, where the consignee or consignor of imported or exported goods or a customs declaration enterprise applies for recordation, it shall obtain the qualification of market entities; particularly where the consignee or consignor of imported or exported goods applies for recordation, it shall be filed as a foreign trade business. Where the consignee or consignor of imported or exported goods or a customs declaration enterprise has undergone the formalities of recordation for customs declaration entities, branches that meet the requirements of the preceding paragraph may also apply for recordation for customs declaration entities.

REGULATIONS IN RELATION TO THE "FULL CIRCULATION" OF H-SHARE

On November 14, 2019, CSRC announced the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請"全流通"業務指引》) (the "Guidelines for the 'Full Circulation'"). According to the Guidelines for the "Full Circulation", "Full circulation" means listing and circulating on the Stock Exchange of the domestic unlisted shares of an H-share listed company,

including [**REDACTED**] Domestic Shares held by domestic shareholders prior to overseas [**REDACTED**], [**REDACTED**] Domestic Shares additionally issued after overseas [**REDACTED**], and [**REDACTED**] shares held by foreign shareholders. Shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for "Full Circulation". To file an application for "Full Circulation", an H-share listed company shall file the application with the CSRC according to the administrative licensing procedures necessary for the "examination and approval of public issuance and listing (including additional issuance) of shares overseas by a joint stock company". An H-share listed company may apply for "Full Circulation" separately or when applying for refinancing abroad. An unlisted domestic joint stock company may apply for "Full Circulation" when applying for an overseas [**REDACTED**]. After the application for "Full Circulation" has been approved by the CSRC, an H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the conversion registration with the CSDC of the shares related to the application has been completed. After domestic unlisted shares are listed and circulated on the Stock Exchange, they may not be transferred back to China.

On December 31, 2019, CSDC and Shenzhen Stock Exchange (the "**SZSE**") jointly announced the Measures for Implementation of H-share "Full Circulation" Business (《H股"全流通"業務實施細則》) ("**Measures for Implementation**"). The businesses of cross-border conversion registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. in relation to the H-share "Full Circulation" business, are subject to the Measures for Implementation. Where there is no provision in the Measures for Implementation, it shall be handled with reference to other business rules of the CSDC and China Securities Depository and Clearing (Hong Kong) Company Limited (the "**CSDC (Hong Kong)**") and SZSE. According to the Measures for Implementation, after having completed relevant information disclosure, the H-share listed companies with the approval of the CSRC to engage in the H-share "Full Circulation" business shall apply to the CSDC for the deregistration of part or all of the domestic unlisted shares, and shall transfer the fully circulated H-shares which are not pledged, frozen, restricted to transfer to the share register institutions in Hong Kong. Such shares shall become eligible for listing and circulation on the Stock Exchange. Relevant securities are centrally deposited in CSDC for settlement. As the nominal holder of the above-mentioned securities, CSDC handles the depository and holding details maintenance,cross-border clearing and settlement and other businesses involved in the "Full Circulation" of H-shares, and provides nominal holder services for investors. The H-share listed company shall be authorized by "fully-tradable" shareholders to choose domestic securities companies that participate in the "Full Circulation" business of H-shares. Investors submit trading instructions of H-shares "fully tradable" shares through domestic securities companies. Domestic securities companies shall select a Hong Kong securities company to submit trading instructions of the investors to the Stock Exchange for trading. After the transaction is concluded, CSDC and CSDC (Hong Kong) shall handle the cross-border clearing and settlement of relevant shares and funds. The

settlement currency of H-share "Full Circulation" transaction business is Hong Kong dollars. Where an H-share listed company entrusts CSDC to distribute cash dividends, it shall file an application with CSDC. An H-share listed company distributing cash dividends may apply to the CSDC for the holding details of relevant "fully-tradable" shareholders on the securities registration date. The non-H-share "fully circulated" securities listed on the Stock Exchange obtained due to the distribution or conversion of H-shares "fully circulated" securities may be sold but shall not be purchased. Where the right to subscribe for the shares listed on the Stock Exchange is obtained and the subscription right is listed on the Stock Exchange, it may be sold, but shall not be exercised.

In order to fully promote the reform of H-shares "Full Circulation" and clarify the business arrangement and procedures for the relevant shares' registration, custody, settlement and delivery, CSDC has promulgated the Circular on Issuing the Guide to the Program for Full Circulation of H-shares (《關於發佈〈H股"全流通"業務指南〉的通知》) in February, 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, etc. According to the Circular on Issuing the Guide to the Program for Full Circulation of H-shares (《關於發佈〈H股"全流通"業務指南〉的通知》), if the qualification of the "Full Circulation" of H-shares is approved together with the company's overseas listing refinancing or [**REDACTED**] application, the shares involved are overseas listed shares, and there is no need to register and settle with China Securities A limited liability company for the initial registration of non-overseas listed shares.

REGULATIONS IN RELATION TO EMPLOYMENT AND SOCIAL SECURITIES

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by the SCNPC on July 5, 1994 and latest amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), promulgated by the SCNPC on June 29, 2007 and latest amended on December 28, 2012 and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, working location, occupational hazards, and status of safe production as well as remuneration and other conditions.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and latest amended on December 29, 2018, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was amended by the State Council on March 24, 2019, employers and/or employees are required to contribute to a number of social security funds, including funds for basic pension insurance, employment insurance, basic medical insurance, occupational injury insurance, maternity leave insurance, and to housing provident funds. These payments are made to local administrative authorities and employers who fail to contribute may be fined and ordered to rectify within a stipulated time limit.

LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

U.S. government regulation of drug and biological products

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "**FDCA**"), its implementing regulations and biologics under the FDCA and the Public Health Service Act (the "**PHSA**") and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Once a product candidate is identified for development, it enters pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application ("**IND**") must submit the results of the pre-clinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board ("**IRB**"), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at **www.clinicaltrials.gov**.

Concurrent with clinical trials, companies may complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with current Good Manufacturing Practice ("**cGMP**"), requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. review and approval processes

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a BLA. Unless deferred or waived, BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the BLA to ensure that it is sufficiently complete for substantive review before it accepts the BLA for filing. After accepting the BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase 4 clinical trials, to further assess a product's safety and effectiveness after BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited development and review programs

Accelerated approval

Under FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("**IMM**"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may allow the FDA to consider to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstances.

United States regulatory framework for biosimilars

An abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009 (the "**BPCIA**"), enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. The BPCIA established this abbreviated pathway under section 351(k) of the PHSA, consequently biosimilar applications are also called 351(k) applications or abbreviated BLAs ("**aBLAs**"). Biosimilar products are "highly similar" to the reference product ("**RP**") notwithstanding "minor differences" in clinically-inactive components, and must demonstrate to the FDA that there are no clinically-meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications, which the FDA has continued to expand on over time. For instance, the FDA has expanded its guidance for interchangeable biosimilars, which may be substituted for their RP counterpart without additional physician intervention, similar to generic drugs in most states.

In general, approval of a biosimilar product requires applicants to demonstrate that the biological product is biosimilar to a reference product based upon data derived from:

(a) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically-inactive components;

(b) animal studies (including the assessment of toxicity); and

(c) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the RP is licensed and intended to be used and for which licensure is sought for the biological product.

The FDA, moreover, has the discretion to waive one or more of these requirements as it deems appropriate.

In particular, the FDA has discretion over the kind and amount of scientific evidence — laboratory, preclinical and/or clinical — required to demonstrate biosimilarity to a licensed biological product. According to FDA guidance:

> The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

The FDA intends to consider the totality of the evidence, provided by a sponsor to support a demonstration of biosimilarity, and recommends that sponsors use a stepwise approach in the development of their biosimilar products. Biosimilar product applications thus may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product. However, the FDA may refuse to approve a biosimilar application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The submission of an application via the 351(k) pathway does not guarantee that the FDA will accept the application for filing and review, as the FDA may refuse to accept applications that it finds are insufficiently complete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any applicable user fees assessed under the applicable Biosimilar User Fee Act have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical studies and submit a BLA for licensure as a new biological product under section 351(a) of the PHSA.

In addition, addition, an application submitted under the 351(k) pathway must include information demonstrating that:

(a) the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;

(b) the condition or conditions of use prescribed, recommended, or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;

(c) the route of administration, the dosage form, and the strength of the proposed biosimilar product are the same as those for the reference product; and

(d) the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Section 351(k)(4) of the PHSA provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

(a) the proposed product is biosimilar to the reference product;

(b) the proposed product is expected to produce the same clinical result as the reference product in any given patient; and

(c) for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

There have been nearly 40 biosimilar product applications approved by the FDA under the 351(k) pathway to date, three of which have been deemed "interchangeable" with their reference product BLA counterpart, which were approved for the first time in 2021. Market acceptance of biosimilar products in the United States was initially uncertain but has continued to improve since enactment of the BPCIA. Some states have enacted laws that provide additional biosimilar regulation or oversight that may restrict the substitution by state pharmacies of biosimilars for reference products already licensed by the FDA. Such regulations may include biosimilar substitution notification to prescribing physicians other prescribing healthcare professionals, including for interchangeable biosimilars. Market success of biosimilar products continues to depend on demonstrating to patients, physicians, payors and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

The BPCIA requires a biosimilar applicant to demonstrate biosimilarity with respect to a reference biological product that has been approved by FDA in the United States. Biosimilars approved in the European Union ("**EU**") and other non-U.S. jurisdictions may not be approved in the U.S. without additional "bridging" studies demonstrating biosimilarity to an FDA-approved reference product. Biosimilars approved in the U.S. may also not be approved in foreign jurisdictions without additional bridging studies. The requirements for such bridging studies vary from product to product, which may require clarification in product development meetings with the FDA for product candidates.

As a result, biosimilar companies must continue to analyze and incorporate into their biosimilar development plans any final regulations or guidance issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements established by relevant authorities. The costs of development and approval, along with the probability of success for any biosimilar product candidate will depend upon application of the laws and regulations issued by the relevant regulatory authorities.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the RP is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the RP. The FDA cannot approve a biosimilar application for 12 years from the date of first licensure of the reference product. In some instances, a subsequent period of 12 years of exclusivity may also be granted for structural changes (e.g., amino acid sequence, post-translational events, infidelity of translation or transcription, glycosylation patters or tertiary structure, or differences in biological activity) that result in changes in safety, purity, or potency to previously-approved biological products. Additionally, a biosimilar product sponsor may not submit an application under the 351(k) pathway for four years from the date of first licensure of the reference product.

A reference product may also be entitled to exclusivity under other statutory provisions. For example, RP that is designated and approved as an orphan drug may be entitled to seven years of exclusivity under section 360cc of the FFDCA, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve year period provided under §351(k) or the end of the seven year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block §351(k) applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first 351(k) application to obtain FDA determination of interchangeability is entitled to a certain period of exclusivity (not first to file a biosimilar application). The exclusivity attaches based on determination of interchangeability for any condition of use and prevents a determination that another product is interchangeable but does not prevent approval of additional biosimilar products. In addition, this interchangeable a BLA exclusivity period is subject to forfeiture. Specifically, the interchangeable biosimilar exclusivity extends for:

(a) one year after first commercial marketing; or

(b) 18 months after either

  (i) a final court decision on all patents in suit in a patent infringement action instituted against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

  (ii) the dismissal with or without prejudice of an action instituted under the same provision against the application that submitted the application for the first approved interchangeable product; or

(c) (i) 42 months after approval of the first interchangeable biosimilar biological product, if the applicant that submitted such application has been sued for patent infringement and the litigation is still ongoing; or

  (ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued for patent infringement.

The BPCIA is complex and continues to be interpreted and implemented by the FDA and courts. As a result, its ultimate impact, implementation and meaning are evolving and subject to significant uncertainty. For example, the Federal Circuit has interpreted the BPCIA as requiring (under certain circumstances) the biosimilar applicant to give the reference product sponsor ("**RPS**") 180 days' notice of commercial launch after receiving approval from FDA. This could result in an additional six months of market exclusivity for the reference product. Patent infringement litigation under the BPCIA may also be complex and time-consuming. RPSs may seek preliminary injunctions barring launch during the pendency of such litigation, which could substantially delay market entry. Future implementation decisions by the FDA or court decisions could result in delays in the development or commercialization of biosimilar product candidates or increased costs to assure regulatory compliance and could adversely affect our operating results by restricting or significantly delaying the ability to market new biosimilar products.

Post-marketing requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting

products for unapproved uses or patient populations (known as "**off-label use**") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally-available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("**REMS**"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We may rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to

the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;

- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or

- injunctions or the imposition of civil or criminal penalties.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the "**ACA**") became law in the United States March 2010, and has driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed, for example, the Tax Act enacted by the Congress in 2017, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated on January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, on January 1, 2021, eliminated the health insurer tax. In the future there may be other efforts to challenge, repeal or replace the ACA that impact our business.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

LAWS AND REGULATIONS IN THE EU

This section summarizes the principal laws and regulations in the EU that are relevant to our business.

LAWS AND REGULATIONS IN RELATION TO MEDICINAL PRODUCTS

The legal framework in the EU is based both on EU legislation and national legislation of the member states of the EU (the "**Member States**" or each a "**Member State**"). For human medicinal products the two main instruments of the EU legal framework for medicinal products are Regulation (EC) No 726/2004 which is binding to the Member States and Directive 2001/83/EC which is implemented into the national legislation. The two regulatory documents stipulate that for a medicinal product to be placed on the European market, it must be subject to a Marketing Authorization ("**MA**") issued by the relevant competent authority. There are different options to gain a MA: the Centralized Procedure ("**CP**") according to Regulation (EC) No 726/2004, the Decentralized Procedure ("**DCP**") or the Mutual Recognition Procedure ("**MRP**") according to Directive 2001/83/EC or a purely national procedure.

These two key EU legal documents complemented by further legislation provide the EU regulatory framework for human medicinal products. Furthermore, the European Medicines Agency ("**EMA**") issues scientific guidelines on medicinal products to help pharmaceutical companies to prepare marketing authorization applications ("**MAA**") for human medicinal products.

By using the described procedures, it is possible to achieve MA for medicinal products in the European Economic Area ("**EEA**"). The 27 Member States of the EU together with Norway, Iceland and Liechtenstein form the EEA. These countries have, through the EEA agreement, adopted the complete EU acquis on medicinal products and are consequently parties to the EU procedures.

EU REVIEW AND APPROVAL PROCESSES

The results of medicinal product development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed summary of product characteristics, package leaflet and labelling and other relevant information are submitted to the relevant competent authority in the EU for assessment. The data submitted by medicine developers in their MAA must comply with EU legislation.

The following procedures are available for the medicine developers:

Centralized procedure

The CP is mandatory for certain types of medicinal products. Medicinal products under the mandatory scope belong to one of the following categories:

- Medicinal products developed by means of one of the following biotechnological processes: recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody methods.

- Medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of any of the following diseases: acquired immune deficiency syndrome, cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other auto-immune dysfunctions and viral diseases.

- Medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

Additionally, the CP may be used for further products. Medicinal products falling under the optional scope are medicinal products containing a new active substance, constituting a significant innovation or the granting of authorization is in the interest of patients at EU level.

The assessment of an application for a new medicine takes up to 210 active days. This active evaluation time is the time spent by EMA experts to evaluate the evidence provided by the applicant in support of a MAA. This time is interrupted by one or two clock-stops during which the applicant prepares the answers to any questions raised by the Committee for Medicinal Products for Human Use ("**CHMP**").

Accelerated assessment or the grant of MA subject to post-authorization conditions are possible.

At the end of the CP with a positive agreement the EMA issues a recommendation to the European Commission which then takes a final legally binding decision on whether the medicinal product can be marketed in the EU. This decision is issued within 67 days of receipt of EMA's recommendation.

Decentralized procedure or mutual recognition procedure

For medicinal products not falling within the mandatory scope of the CP the applicant must be used for MAA for medicinal products in more than one Member State either the DCP in case the medicinal product in question has not received a MA in any Member State or the MRP in case the medicinal product in question has already received a MA in any Member State.

Both the DCP and the MRP are based on the recognition by national competent authorities of an assessment performed by the authorities of one Member State.

In the MRP the Reference Member State ("**RMS**") drafts an assessment report and provides this report together with the approved summary of product characteristics, labelling and package leaflet to concerned Member States. Within 90 days of the receipt of these documents, the concerned Member States shall recognize the decision of the reference Member State and the approved summary of product characteristics, package leaflet and labelling by granting a marketing authorization with a harmonized summary of product characteristics, package leaflet and labelling. The applicant addresses questions during a clock stop period and sends the response document to the RMS and the concerned Member States.

In the DCP the RMS shall supply the draft assessment report, summary of product characteristics, package leaflet and labelling to the concerned member states and the applicant not later than 120 days after the validation of the application. The RMS may close the DCP if consensus already reached. In case no consensus is reached all concerned Member States have 90 days in a further assessment stage to approve the assessment report, the summary of product characteristics and the labelling and package leaflet. The applicant addresses questions during clock stop periods and sends the response documents to the RMS and the concerned Member States.

At the end of the MRP and DCP with a positive agreement national MAs will be issued in the Member States.

National procedure

MAA for medicinal products in one Member State only are submitted to the national competent authority of the Member State. The competent authority assesses the MAA based on national legislation. In case of positive assessment, the MA is issued with effect for this Member State.

GUIDANCE DOCUMENTS FOR BIOLOGICAL MEDICINAL PRODUCTS

A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterization and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.

The EMA guidelines on biological human medicines reflect a harmonized approach of the Member States and the EMA on how to interpret and apply the requirements for the demonstration of quality, safety and efficacy set out in the EU legislation.

Guidelines on biological medicinal products are provided both for the active substance and the finished product.

GUIDANCE DOCUMENTS FOR BIOSIMILAR PRODUCTS

A biosimilar is a biological medicinal product highly similar to another already approved biological medicinal product in the EEA, for which marketing exclusivity rights have expired. At the time of submission of the similar biological application, the data exclusivity period of the reference medicinal product should have expired which is eight years after the date of notification of the MA of the reference medicinal product in accordance with Art. 10 of Directive 2001/83/EC. The EMA is responsible by way of the Centralized Procedure for the assessment and grant of MA of biosimilar medicinal products in the EEA.

Developers of biosimilars are required to demonstrate through comparative studies with the reference biological medicinal product that:

- the biosimilar is highly similar to the reference medicinal product, notwithstanding natural variability inherent to all biological medicines; and

- there are no clinically-meaningful differences between the biosimilar and the reference medicine in terms of safety, quality and efficacy.

Comparability is conceived in a step-wise process that is adapted for each product. Based on initial quality comparability studies the extent and type of non-clinical and clinical studies required in the next step of development is determined. This step-wise process needs to take into account the specific characteristic of each individual medicinal product. The EMA offers scientific advice to support the step-by-step development of new biosimilars.

In particular the following guidelines define the regulatory requirements for biosimilars in the EU:

- ICH Q5E Biotechnological/biological products subject to changes in their manufacturing process: comparability of biotechnological/biological products (CPMP/ICH/5721/03)

- Guideline on similar biological medicinal products (CHMP/437/04 Rev 1)

- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – quality issues (EMA/CHMP/BWP/247713/2012)

- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues (EMEA/CHMP/BMWP/42832/2005 Rev 1)

Clinical trials performed in support of the MAA need to comply with the specific provisions regarding the conduct of these clinical trials on human subjects in line with the implementation of good clinical practice by Directive 2001/20/EC.

The legal basis of Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to this Directive lay down the requirements for the MAAs based on the demonstration of the similar nature of the two biological medicinal products.

PRICING AND REIMBURSEMENT IN THE EU

The pricing and reimbursement for medicinal products in the Member States of the EU is governed by national legislation of the Member States.

OVERVIEW

We are a highly integrated biopharmaceutical company committed to developing, manufacturing and commercializing high quality biologics in China and overseas. Our history can be traced back to December 2013 when Shandong International Biotechnology Development Co., Ltd. (山東國際生物科技園發展有限公司) ("**Biotech Park Development**") established our Company to engage in therapeutic antibody development. Biotech Park Development was an investment holding company with a focus on investments in biomedicine and healthcare sectors, and was owned as to 67.0% indirectly by Mr. Liu Dian Bo, Mr. Yang Rong Bing and Mr. Yuan Hui Xian (each an executive director and a founder of Luye Pharma) (the "**Luye Founders**") and 33.0% by Yantai Gaoxin State-Owned Assets Management Company Limited (煙台高新國有資產管理有限公司) ("**Yantai Gaoxin**"). In February 2020, with a view to tapping into the fast growing field of biopharmaceuticals, Luye Pharma, through its wholly-owned subsidiary, acquired 98.0% equity interest in our Company, since then we have become a subsidiary of Luye Pharma.

Over the years of development, we have accumulated extensive experience in areas of antibody discovery, cell line development as well as upstream and downstream process development, and have developed a robust product portfolio covering key types of biologics, including [eight] innovative antibody candidates with international intellectual property protection and [five] biosimilar drug candidates.

OUR BUSINESS MILESTONES

We set forth below our key business development and milestones:

Time	Milestone
December 2013	• Our Company was established in the PRC
January 2014	• Our 200L pilot plant came into operation
September 2016	• Investigational new drug (IND) of BA1101 was approved in China
November 2016	• We obtained the patent for "a preparation method of transgenic animal expressing human antibody" in China
April 2017	• BA1101 entered into Phase 1 clinical trial in China
May 2017	• Investigational new drug (IND) of BA6101, one of our Core Products, was approved in China
June 2017	• Investigational new drug (IND) of BA1102, one of our Core Products, was approved in China

Time	Milestone
December 2017	• BA1101 entered into Phase 3 clinical trial in China
	• BA6101 entered into Phase 1 clinical trial in China
March 2019	• Investigational new drug (IND) of BA9101 was approved in China
June 2019	• BA6101 entered into Phase 3 clinical trial in China
	• BA9101 entered into Phase 1 clinical trial in China
February 2020	• Our Company became a subsidiary of Luye Pharma, which, through its wholly-owned subsidiary, acquired 98% equity interest in our Company
June 2020	• Investigational new drug (IND) of BA6101 was approved in the US
October 2020	• Clinical trial application of BA6101 was approved in Germany
January 2021	• BA1102 entered into Phase 3 clinical trial
	• We completed our first round of fund raising — Series A Investments, raising gross proceeds of approximately RMB876 million in aggregate
February 2021	• BA9101 entered into Phase 3 clinical trial
April 2021	• BA1101 was approved by the NMPA to launch in China
May 2021	• LY-CovMab, one of our Core Products, completed its Phase 1 clinical trial
September 2021	• We completed a further round of fund raising — Series B Investments, raising gross proceeds of approximately RMB210.9 million in aggregate
	• Investigational new drug (IND) of BA5101, one of our pipeline products, was approved in China
	• Investigational new drug (IND) of BA1105, one of our pipeline products, was approved in China

Time	Milestone
October 2021	• Our application for the marketing authorization for BA6101, one of our Core Products, was accepted by the NMPA
December 2021	• Investigational new drug (IND) of BA1201, one of our pipeline products, was approved in China
February 2022	• BA5101 entered into the formal trial of the Phase 1 clinical trial in China
July 2022	• BA5101 entered into Phase 3 clinical trial in China
September 2022	• Investigational new drug (IND) of BA-CovMab, one of our pipeline products, was approved in China
	• Investigational new drug (IND) of BA1106, one of our pipeline products, was approved in China
October 2022	• Investigational new drug (IND) of BA2101, one of our pipeline products, was approved in China
November 2022	• BA6101 received the regulatory approval to commence commercialization in China

OUR CORPORATE DEVELOPMENTS

Our Company

Establishment

Our Company was established in the PRC as a limited liability company on December 30, 2013 with an initial registered capital of RMB10,000,000. At the time of establishment, our Company was wholly owned by Biotech Park Development, a company owned as to 67.0% by a company wholly-owned by Luye Investment Group Co. Ltd. (綠葉投資集團有限公司) ("**LIG**"), which was in turn wholly-owned by the Luye Founders, and 33.0% by Yantai Gaoxin. Yantai Gaoxin is a PRC local government instrumentality and an Independent Third Party. The Luye Founders and Yantai Gaoxin became acquainted in 2013 when the local government of Yantai sought for influential companies for investments and business collaborations in the area.

In light of our development plans and expected need for further increased funds to finance our expansion plan, Yantai Gaoxin decided to exit from our Company in 2019. To implement the exit for Yantai Gaoxin, on June 18, 2019, LIG and Yantai Gaoxin procured Biotech Park Development to transfer its entire equity interest in our Company to Yantai Lvchuang Biotechnology Co., Ltd. (煙台綠創生物科技有限公司) (a company wholly-owned by the Luye Founders, "**Yantai Lvchuang**") at a consideration of RMB20 million. The consideration was determined after arm's length negotiations between the parties with reference to the net asset value of our Company as of April 30, 2019 as appraised by an independent valuer.

Subsequently LIG undertook a corporate restructuring, pursuant to which on October 11, 2019, Yantai Lvchuang transferred its entire equity interest in our Company to LIG at a consideration of RMB36 million. The consideration was determined after arm's length negotiations between the parties with reference to the net asset value of our Company as of April 30, 2019 as appraised by an independent valuer and taking into account that after the date of such appraisal, our two drug candidates, BA9101 and BA6101, entered into Phase 1 and 3 clinical trial in China, respectively, in June 2019.

Further on December 5, 2019, LIG transferred a 2% equity interest in our Company to Thinktank Capital Management Holdings Limited (智庫資本管理集團有限公司) ("**Thinktank**"), an Independent Third Party, at a consideration of US$4.2 million. The consideration was determined after arm's length negotiations between the parties with reference to the net asset value of our Company as of April 30, 2019 as appraised by an independent valuer and taking into account the aforesaid progress in the development of our drug candidates, BA9101 and BA6101, in June 2019, and our drug candidate, BA1102, entered into Phase 1 clinical trial in China in December 2019.

Acquisition of our Company by Shandong Luye

With a view to further expanding and diversifying its pipeline portfolio and further accelerating its growth and penetration in the fast-growing biopharmaceutical sub-segment, Luye Pharma (through its wholly owned subsidiary, namely Shandong Luye) acquired 98% equity interest in our Company in February 2020 for RMB1,446.7 million. The consideration was determined after arm's length negotiations between the parties with reference to the entire equity interest value of our Company as of June 30, 2019 as assessed by an independent valuer (which was primarily based on the then value of our biosimilar and innovative products) and was settled in May 2021, save for RMB361.7 million which shall be payable upon the grant by the competent authority in China of the marketing authorization for BA6101, the BLA of which had been accepted by the NMPA in October 2021.

On June 23, 2020, Shandong Luye acquired the remaining 2% equity interest in our Company from Thinktank for US$5,720,000, which was determined after arm's length negotiations between the parties with reference to the then net asset value of our Company. The consideration was fully settled in June 2020. Upon completion of such equity transfer, our Company became wholly owned by Shandong Luye.

Establishment of employee share incentive plan

We established an employee share incentive plan with the aim to incentivize employees of our Group and retain them for continuing service for development of our Group, and to attract suitable personnel for our Group's long-term growth.

Each of the ESOP Entities was a limited partnership established in China for holding equity interest in our Company on behalf of our employees pursuant to the employee share incentive plan. In December 2020, Yantai Bolian, Yantai Bosheng and Yantai Bofa contributed capital to our Company in the amount of RMB21,380,000, RMB14,930,000 and RMB11,250,000, respectively, with funds contributed from the partners of the ESOP Entities, who are employees of our Group. Upon completion of such capital injection, our Company became owned as to approximately 88.33% by Shandong Luye, 5.25% by Yantai Bolian, 3.66% by Yantai Bosheng and 2.76% by Yantai Bofa.

As of the Latest Practicable Date, the general partner of Yantai Bolian was Ms. Li Li, our non-executive Director, who held approximately [3.84]% equity interest in Yantai Bolian, and its limited partners were [48] employees of our Group. Ms. Li Li as the general partner of Yantai Bolian is entitled to exercise the voting rights held by Yantai Bolian in our Company at her discretion. Ms. Jiang Hua (our chairlady, chief executive officer and one of our executive Directors), Dr. Dou Changlin (our president of R&D, chief operating officer and one of our executive Directors), Dr. Li Youxin (our vice chairman and one of our non-executive Directors) and Mr. Lu Jun (our senior vice president and head of biotechnology engineering center and quality department) held approximately [22.08]%, [31.81]%, [7.02]% and [18.71]% interest in Yantai Bolian, respectively. Save as disclosed above, none of our Directors and Supervisors held any interest in Yantai Bolian and none of the limited partners held 5% or more interest in Yantai Bolian as of the Latest Practicable Date.

As of the Latest Practicable Date, the general partner of Yantai Bosheng was Ms. Li Li, our non-executive Director, who held approximately [10.65]% equity interest in Yantai Bosheng, and its limited partners were [47] employees of our Group. Ms. Li Li as the general partner of Yantai Bosheng is entitled to exercise the voting rights held by Yantai Bosheng in our Company at her discretion. Ms. Jiang Hua (our chairlady, chief executive officer and one of our executive Directors), Mr. Liu Yuanchong (one of our non-executive Directors) and Mr. Wang Shenghan (our chief financial officer) held approximately [16.61]%, [20.09]% and [22.30]% interest in Yantai Bosheng, respectively. Save as disclosed above, none of our Directors and Supervisors held any interest in Yantai Bosheng and none of the limited partners held 10% or more interest in Yantai Bosheng as of the Latest Practicable Date.

As of the Latest Practicable Date, the general partner of Yantai Bofa was Ms. Li Li, our non-executive Director, who held approximately [9.69]% equity interest in Yantai Bofa, and its limited partners were [47] employees of our Group. Ms. Li Li as the general partner of Yantai Bofa is entitled to exercise the voting rights held by Yantai Bofa in our Company at her discretion. Ms. Jiang Hua (our chairlady, chief executive officer and one of our executive Directors), Mr. Liu Yuanchong (one of our non-executive Directors), Mr. Wang Shenghan (our chief financial officer) and Mr. Song Deyong (our head of biopharmaceutical research and discovery department) held approximately [16.00]%, [8.89]%, [14.31]% and [8.00]% interest in Yantai Bofa, respectively. Save as disclosed above, none of our Directors and Supervisors held any interest in Yantai Bofa and none of the limited partners held 5% or more interest in Yantai Bofa as of the Latest Practicable Date.

Pursuant to the respective partnership agreements entered into between each ESOP Entity and its partners, (i) the ESOP Entity shall not dispose of any of the Shares it held within 12 months immediately following the date of [**REDACTED**] (the "**ESOP Lock-up Period**"); and (ii) a partner is entitled to direct the ESOP Entity to dispose of his/her share of the Shares held by the ESOP Entity (based on his/her shareholding percentage in the ESOP Entity) (the "**ESOP Shares**") in the proportion and on the respective dates as follows:

(a) 25% of his/her ESOP Shares upon the expiry of 12 months following the day after the ESOP Lock-up Period;

(b) 50% of his/her ESOP Shares upon the expiry of 24 months following the day after the ESOP Lock-up Period;

(c) 75% of his/her ESOP Shares upon the expiry of 36 months following the day after the ESOP Lock-up Period; and

(d) 100% of his/her ESOP Shares upon the expiry of 48 months following the day after the ESOP Lock-up Period.

Following the disposal, the ESOP Entity will transfer the net sale proceeds to the relevant partner. The voting rights of the Shares held by the ESOP Entities are exercisable by their respective general partners.

Series A Investments

In the course of December 2020 and January 2021, we entered into agreements with investors indicated below (the "**Series A Investors**") who agreed to invest in and subscribe for equity in our Company by capital contributions in the aggregate amount of RMB876,617,600.

The capital contribution amount from the Series A Investors was determined after arm's length negotiations with our Company with reference to a pre-money valuation of our Company of approximately RMB4,723 million based on, among other things, the R&D capabilities of our Group, our product pipelines and market potential, and the overall landscape of the biotech industry in China. The capital contributions of the Series A Investors were settled in cash in full in January 2021. The following table sets forth the list of equity holders of, and their respective equity interest in, our Company upon completion of the aforesaid capital contributions:

Name of equity holder *(Note 1)*	**Date of investment agreement**	**Series A investment amount**	**Approximate percentage of equity interest upon completion of Series A investment**
		(RMB)	
Shandong Luye	–	–	74.50%
Yantai Bolian	–	–	4.42%
Yantai Bosheng	–	–	3.09%
Yantai Bofa	–	–	2.33%
SIP Sungent	December 19, 2020	100,000,000	1.79%
SZ BioResearch *(Note 2)*	December 22/29, 2020	70,000,000	1.25%
Yantai Innovative	December 23, 2020	10,000,000	0.18%
Yantai Blue Ocean	December 28, 2020	50,000,000	0.89%
Nanjing Ruiyuan	December 28, 2020	10,000,000	0.18%
Qianhai Equity Fund	December 30, 2020	70,000,000	1.25%
Serendipity Investment	December 30, 2020	65,256,000	1.17%
Zhongyuan Qianhai	December 30, 2020	30,000,000	0.54%
SZ Xingrui	December 30, 2020	10,000,000	0.18%
Asian Alliance	December 30, 2020	6,525,600	0.12%
Advantech Capital	December 31, 2020	150,000,000	2.68%
Brill Aimei	December 31, 2020	60,000,000	1.07%
Brill Luoyi	December 31, 2020	30,000,000	0.54%
Qianhai Weiyang	December 31, 2020	20,000,000	0.36%
Hainan Wensen	January 19, 2021	10,000,000	0.18%
CCB Juyuan	January 25, 2021	100,000,000	1.79%
Starr International	January 25, 2021	64,836,000	1.16%
Yantai Bohui	January 25, 2021	20,000,000	0.36%
Total		**876,617,600**	**100.00%**

Notes:

1. Save for Shandong Luye, Yantai Bolian, Yantai Bosheng and Yantai Bofa, these equity holders are referred to as the Series A Investors.

2. SZ BioResearch entered into two investment agreements with Boan Biotech dated December 22, 2020 and December 29, 2020 in respect of its investment of RMB30 million and RMB40 million in Boan Biotech, respectively.

Conversion into a joint stock limited liability company

We converted into a joint stock limited liability company with 484,000,000 Shares on March 29, 2021. On March 23, 2021, the then equity holders of our Company passed resolutions approving, among other matters, the conversion of our Company from a limited liability company into a joint stock limited liability company. Pursuant to the promoters' agreement dated March 23, 2021 entered into by all the then equity holders of our Company, all promoters approved the conversion of the net asset value of our Company as of January 31, 2021 into 484,000,000 Shares at a ratio of approximately 1:0.33. On March 23, 2021, our Company convened our inaugural meeting and our first general meeting, and passed related resolutions approving the conversion into a joint stock limited liability company and the articles of association. Upon completion of such conversion, the registered capital of our Company became RMB484,000,000 divided into 484,000,000 Shares with a nominal value of RMB1 each, which were subscribed by all the then Shareholders in proportion to their respective equity interest in our Company before the conversion. The conversion was completed on March 29, 2021.

Series B Investments

In the course of August and September 2021, we entered into agreements with the investors indicated below (the "**Series B Investors**") who agreed to invest in and subscribe for equity in our Company by capital contributions in the aggregate amount of RMB210,915,400.

The capital contribution amount from the Series B Investors was determined after arm's length negotiations with our Company with reference to a pre-money valuation of our Company of RMB7,000 million. The capital contributions of the Series B Investors were settled in cash in full in September 2021. The following table sets forth the list of equity holders of, and their respective equity interest in, our Company upon completion of the aforesaid capital contributions:

Name of equity holder	**Date of investment agreement**	**Series B investment amount**	**Approximate percentage of equity interest upon completion of Series B investment**
		(RMB)	
Shandong Luye	–	–	72.32%
Yantai Bolian	–	–	4.30%
Yantai Bosheng	–	–	3.00%
Yantai Bofa	–	–	2.26%
SIP Sungent	–	–	1.73%
CCB Juyuan	–	–	1.73%
SZ BioResearch	–	–	1.21%
Qianhai Equity Fund	–	–	1.21%
Serendipity Investment	–	–	1.13%
Starr International	–	–	1.12%
Brill Aimei	–	–	1.04%
Yantai Blue Ocean	–	–	0.87%
Zhongyuan Qianhai	–	–	0.52%
Brill Luoyi	–	–	0.52%
Qianhai Weiyang	–	–	0.35%
Yantai Bohui	–	–	0.35%
Yantai Innovative	–	–	0.17%
Nanjing Ruiyuan	–	–	0.17%
SZ Xingrui	–	–	0.17%
Asian Alliance	–	–	0.11%
GTJA Huike *(Note)*	August 25, 2021	50,000,000	0.69%
Yunnan Felix *(Note)*	August 25, 2021	40,000,000	0.55%
Advantech Capital *(Note)*	September 13, 2021	12,915,400	2.78%
SD New Growth *(Note)*	September 13, 2021	100,000,000	1.39%
Hainan Wensen *(Note)*	September 13, 2021	8,000,000	0.28%
		210,915,400	**100.00%**

Note: These investors are referred to as the Series B Investors.

To the best of our Directors' knowledge, information and belief, each of the Pre-**[REDACTED]** Investors is an Independent Third Party. See "Pre-**[REDACTED]** Investments" for further details on the investments made by the Pre-**[REDACTED]** Investors and their background information.

***Corporate structure of our Company upon completion of the Pre-*[REDACTED] *Investments and the* [REDACTED]**

The following table sets forth the shareholding structure of our Company upon completion of the Pre-**[REDACTED]** Investments and the **[REDACTED]** (without taking into account any Shares which may be issued pursuant to the **[REDACTED]**):

Name of shareholder	Number of Shares upon completion of the Pre-[REDACTED] Investments	Approximate % of shareholding upon completion of the Pre-[REDACTED] Investments	Number of Shares upon completion of the [REDACTED]	Approximate % of shareholding upon completion of the [REDACTED]
Shandong Luye *(Note 4)*	[360,596,456]	[72.32]%	[REDACTED]	[REDACTED]
Yantai Bolian *(Note 4)*	[21,415,548]	[4.30]%	[REDACTED]	[REDACTED]
Yantai Bosheng *(Note 4)*	[14,954,632]	[3.00]%	[REDACTED]	[REDACTED]
Advantech Capital	[13,857,432]	[2.78]%	[REDACTED]	[REDACTED]
Yantai Bofa *(Note 4)*	[11,268,488]	[2.26]%	[REDACTED]	[REDACTED]
SIP Sungent *(Note 4)*	[8,642,788]	[1.73]%	[REDACTED]	[REDACTED]
CCB Juyuan	[8,642,788]	[1.73]%	[REDACTED]	[REDACTED]
SD Jiazhi LP *(Note 1)*	[6,914,286]	[1.39]%	[REDACTED]	[REDACTED]
SZ BioResearch	[6,050,000]	[1.21]%	[REDACTED]	[REDACTED]
Qianhai Equity Fund	[6,050,000]	[1.21]%	[REDACTED]	[REDACTED]
Serendipity Investment *(Note 2)*	[5,640,052]	[1.13]%	[REDACTED]	[REDACTED]
Starr International	[5,603,752]	[1.12]%	[REDACTED]	[REDACTED]
Brill Aimei *(Note 3)*	[5,185,576]	[1.04]%	[REDACTED]	[REDACTED]
Yantai Blue Ocean	[4,321,636]	[0.87]%	[REDACTED]	[REDACTED]
GTJA Huike	[3,457,143]	[0.69]%	[REDACTED]	[REDACTED]
Yunnan Felix	[2,765,714]	[0.55]%	[REDACTED]	[REDACTED]
Zhongyuan Qianhai	[2,592,788]	[0.52]%	[REDACTED]	[REDACTED]
Brill Luoyi *(Note 3)*	[2,592,788]	[0.52]%	[REDACTED]	[REDACTED]
Qianhai Weiyang	[1,728,364]	[0.35]%	[REDACTED]	[REDACTED]
Yantai Bohui	[1,728,364]	[0.35]%	[REDACTED]	[REDACTED]
Hainan Wensen	[1,417,567]	[0.28]%	[REDACTED]	[REDACTED]
Yantai Innovative	[864,424]	[0.17]%	[REDACTED]	[REDACTED]
Nanjing Ruiyuan	[864,424]	[0.17]%	[REDACTED]	[REDACTED]
SZ Xingrui	[864,424]	[0.17]%	[REDACTED]	[REDACTED]
Asian Alliance *(Note 2)*	[563,860]	[0.11]%	[REDACTED]	[REDACTED]
Public Shareholders *(Note 4)*	–	–	[REDACTED]	[REDACTED]
Total	**[498,583,294]**	**100%**	[REDACTED]	**100%**

Notes:

1. To facilitate the application for full circulation of H shares of our Company in connection with the [**REDACTED**], a corporate restructuring was undertaken pursuant to which on February 22, 2022, SD New Growth transferred its entire shareholding interest in our Company to its wholly-owned subsidiary, namely SD Jiazhi LP, at the consideration of RMB100 million, which was determined after arm's length negotiations with reference to the initial investment amount paid by SD New Growth in September 2021, and was settled in full in cash on February 24, 2022.

2. Serendipity Investment and Asia Alliance are ultimately controlled by Dr. Yang Zhi (楊志) and he will be interested in an aggregate of [**REDACTED**] Shares, representing approximately [**REDACTED**]% and [**REDACTED**]% of our share capital upon completion of the Pre-[**REDACTED**] Investments and the [**REDACTED**], respectively.

3. Brill Aimei and Brill Luoyi are both ultimately controlled by Mr. Sun Peng (孫鵬) and he will be interested in an aggregate of [**REDACTED**] Shares, representing approximately [**REDACTED**]% and [**REDACTED**]% of our share capital upon completion of the Pre-[**REDACTED**] Investments and the [**REDACTED**], respectively.

4. Upon completion of the [**REDACTED**], save for the Shares held by Shandong Luye, Yantai Bolian, Yantai Bosheng, Yantai Bofa and SIP Sungent, all the remaining [**REDACTED**] Shares, representing [**REDACTED**]% of our total share capital, will be counted towards the [**REDACTED**] for the purpose of Rule 8.08 of the Listing Rules.

Our PRC Legal Adviser has confirmed that the above mentioned equity transfers, capital increase and joint-stock conversion have been properly and legally completed and all requisite regulatory approvals have been obtained in accordance with the applicable PRC laws and regulations.

Our subsidiaries

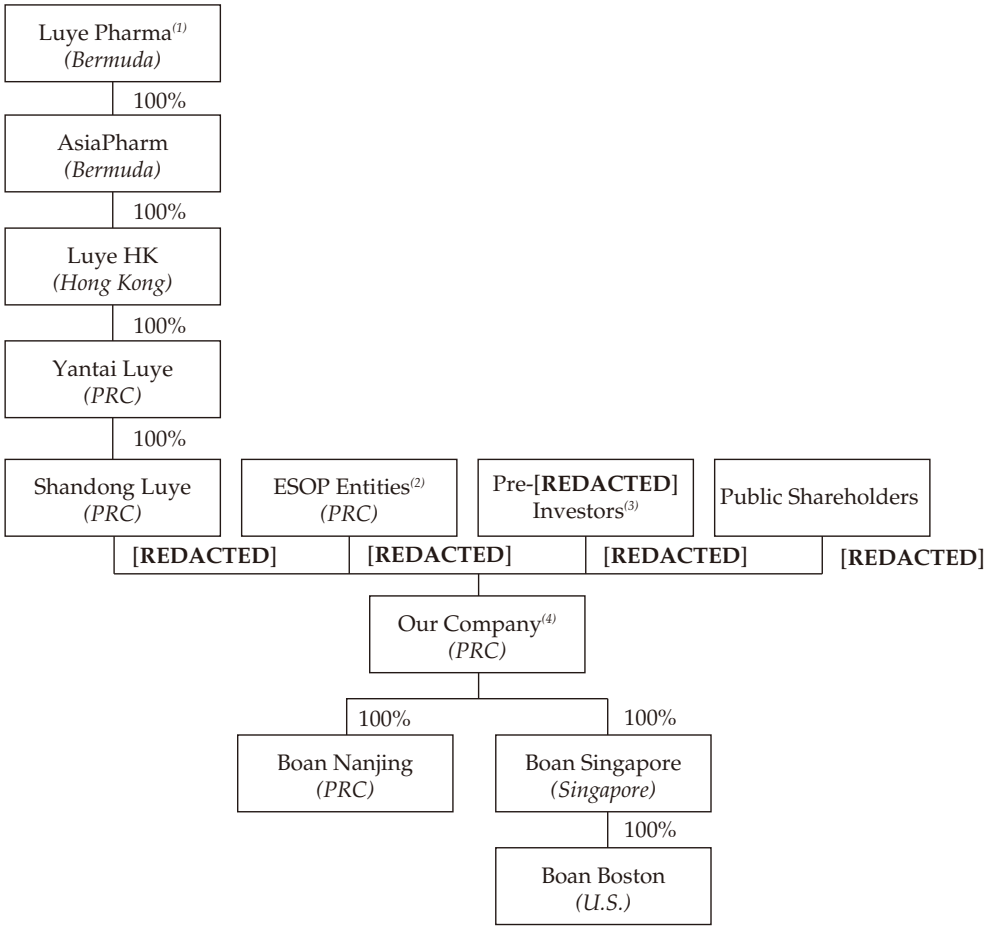
As of the Latest Practicable Date, we have established three subsidiaries for early stage R&D and overseas market development purposes. We established Boan Singapore in Singapore as our base for overseas market development, as we believe that Singapore, as a leading biomedical hub with the presence of many multinational biopharmaceutical corporations, vast R&D resources and a well-developed regulatory framework, is a suitable platform for our Company to grow our overseas business. The principal business activities, date and place of establishment of each of our subsidiaries are set forth below:

Name of subsidiary	Principal business activities	Place and date of establishment
Boan Nanjing	Early stage research and development in new antibody drugs	PRC, July 15, 2020
Boan Boston	Early stage research and development in new antibody drugs	State of Delaware, the U.S., October 20, 2020
Boan Singapore	Overseas market development	Singapore, October 20, 2020

All of the subsidiaries of our Company are directly or indirectly wholly owned by our Company and save as disclosed in "Statutory and General Information — A. Further information about our Group — 6. Change in the registered capital of subsidiaries" in Appendix VI to this document, there have been no material changes in their shareholding since their respective dates of establishment up to the Latest Practicable Date.

SHAREHOLDING AND CORPORATE STRUCTURE IMMEDIATELY AFTER THE [REDACTED]

The following chart sets forth a corporate structure of our Group immediately after completion of the [**REDACTED**] (without taking into account any Shares which may be issued pursuant to the [**REDACTED**]):



Notes:

1. The Shares of Luye Pharma are listed on the Stock Exchange (stock code: 2186).

2. The ESOP Entities and their respective shareholding percentages in our Company are as follows:

Name of ESOP Entities	Approximate % of shareholding
Yantai Bolian	[REDACTED]
Yantai Bosheng	[REDACTED]
Yantai Bofa	[REDACTED]
Total	[REDACTED]

3. The Pre-[**REDACTED**] Investors and their respective shareholding percentages in our Company are as follows:

Name of Pre-[REDACTED] Investor	Approximate % of shareholding
Advantech Capital	[REDACTED]
SIP Sungent	[REDACTED]
CCB Juyuan	[REDACTED]
SD Jiazhi LP	[REDACTED]
SZ BioResearch	[REDACTED]
Qianhai Equity Fund	[REDACTED]
Serendipity Investment	[REDACTED]
Starr International	[REDACTED]
Brill Aimei	[REDACTED]
Yantai Blue Ocean	[REDACTED]
GTJA Huike	[REDACTED]
Yunnan Felix	[REDACTED]
Zhongyuan Qianhai	[REDACTED]
Brill Luoyi	[REDACTED]
Qianhai Weiyang	[REDACTED]
Yantai Bohui	[REDACTED]
Hainan Wensen	[REDACTED]
Yantai Innovative	[REDACTED]
Nanjing Ruiyuan	[REDACTED]
SZ Xingrui	[REDACTED]
Asian Alliance	[REDACTED]
Total	[REDACTED]

Save for those Shares held by SIP Sungent, all of the Shares held by the Pre-[**REDACTED**] Investors, representing a total of approximately [**REDACTED**] of the total issued share capital of our Company upon [**REDACTED**] (assuming that the [**REDACTED**] is not exercised at all), will be counted towards the [**REDACTED**] for the purpose of Rule 8.08 of the Listing Rules.

4. Our Company also operates a branch office in Beijing, China.

5. All of the Shares held by each of our Shareholders will be converted into H Shares upon [**REDACTED**].

[REDACTED] OF OUR GROUP FROM LUYE PHARMA

Luye Pharma considers that the [**REDACTED**] and separate [**REDACTED**] of our Group will be commercially beneficial to Luye Pharma, our Company and our Shareholders as a whole for the following reasons:

(a) the [**REDACTED**] will unlock value of our Company which is at fast-growing stage and provide Luye Pharma and its shareholders an opportunity to realize the value of their investment in our Group under a separate standalone platform for our Group's business;

(b) the [**REDACTED**] will separate our Group's business from the Luye Group's business. Such separation will enable shareholders and investors to appraise the strategies, success factors, functional exposure, risks and returns of our Group and the Luye Group separately and to make or refine their investment decisions accordingly. Investors will have the choice to invest in either one or all of the business of our Group or the Luye Group;

(c) the [**REDACTED**] will enable our Group to build our identity as a separately [**REDACTED**] group, to have a separate fund-raising platform and to broaden our investor base. Direct access to capital markets allows our Group to make equity and/or debt financing to fund our existing operations and future expansion without reliance on Luye, thereby accelerating our expansion, improving its operating and financial management efficiencies, which in turn will provide better return to our Shareholders;

(d) the [**REDACTED**] will enable our Group to enhance its corporate profile, thereby increasing its ability to attract investors for making investments in our Group, which could provide synergy for our Group, and the Luye Group will also benefit from such investments without further capital commitment;

(e) the [**REDACTED**] will increase the operational and financial transparency of and improve the corporate governance of our Company and provide Shareholders and investors with greater clarity on the businesses and financial status of our Group on a standalone basis, and such improvements will help to build investor confidence in forming investment decisions based on their assessment of the performance, management, strategy, risks and returns of our Group;

(f) the [**REDACTED**] will enable more focused development, strategic planning and better allocation of resources for the Luye Group and our Group with respect to their respective businesses. Both the Luye Group and our Group will benefit from the efficient decision-making process under the separate management structure for seizing emerging business opportunities, especially with a dedicated management team for our Group to focus on our development. In addition, the [**REDACTED**] will improve the ability of our Group to recruit, motivate and retain key management personnel; and

(g) upon completion of the [**REDACTED**], we are expected to remain as a subsidiary of Luye Pharma and the Luye Group will thus be able to continue enjoying the benefits from the growth of the project management business notwithstanding the separate [**REDACTED**] of our Group.

Luye Pharma has submitted a [**REDACTED**] proposal to the Stock Exchange pursuant to Practice Note 15 of the Listing Rules. Luye Pharma and our Company will comply with the applicable requirements under Practice Note 15 and other applicable requirements of the Listing Rules regarding the [**REDACTED**].

PRINCIPAL TERMS OF THE PRE-[REDACTED] INVESTMENTS

Set forth below is a summary of the details of the investments by our Pre-[**REDACTED**] Investors who have contributed to the equity capital of our Group and each of whom remained as a Shareholder as of the Latest Practicable Date:

Pre-[REDACTED] Investors	Series A Investors	Series B Investors
Date of the investment	December 19, 2020 December 22, 2020 December 23, 2020 December 28, 2020 December 29, 2020 December 30, 2020 December 31, 2020 January 25, 2021	August 25, 2021 September 13, 2021
Total amount of consideration paid	RMB876,617,600	RMB210,915,400
Basis of consideration[(1)]	Pre-money valuation of our Company in the amount of approximately RMB4,723 million Post-money valuation of our Company in the amount of approximately RMB5,600 million	Pre-money valuation of our Company in the amount of approximately RMB7,000 million Post-money valuation of our Company in the amount of approximately RMB7,211 million
Date on which investment was fully settled	January 29, 2021	September 30, 2021
Cost per Share paid under the Pre-[REDACTED] Investments[(2)]	RMB[**REDACTED**]	RMB[**REDACTED**]
Discount to the mid-point of the indicative [REDACTED] Range[(3)]	Approximately [**REDACTED**]%	Approximately [**REDACTED**]%

Shareholding in our Company immediately upon completion of the [REDACTED]	See "History, Development and Corporate Structure — Shareholding and corporate structure immediately after the [**REDACTED**]" for the Pre-[**REDACTED**] Investors' shareholding in our Company immediately after completion of the [**REDACTED**]
[REDACTED]	We utilized the proceeds from the Pre-[**REDACTED**] Investments to finance our principal business, including but not limited to our R&D activities, and to fund our daily operations. As of the Latest Practicable Date, we have utilized approximately [**REDACTED**]% of the [**REDACTED**] from the Pre-[**REDACTED**] Investments and we expect to continue to utilize the remaining [**REDACTED**] in our ordinary course of business to fund our R&D activities and daily operations.
Lock-up	All Shareholders (including the Pre-[**REDACTED**] Investors) immediately prior to the [**REDACTED**] are subject to a lock-up period of 12 months following the [**REDACTED**] according to the PRC Company Law.
Strategic benefits of the Pre-[REDACTED] Investors brought to our Company	Our Directors are of the view that (i) our Company would benefit from the additional capital provided by the Pre-[**REDACTED**] Investors for our R&D activities and daily operations, as well as the knowledge and experience of our Pre-[**REDACTED**] Investors; and (ii) the Pre-[**REDACTED**] Investments have broadened our shareholder base and demonstrated the Pre-[**REDACTED**] Investors' confidence in the R&D capacities and prospects of our Group. Moreover, our Pre-[**REDACTED**] Investors include experienced investors in the areas of the biotech and/or healthcare industry, who can share their insight on business strategies and provide professional advice on our Group's corporate governance, financial reporting and internal control.

Notes:

(1) The pre-money valuation of our Company increased from RMB4,723 million (for the Series A Investment) to RMB7,000 million (for the Series B Investment) primarily due to the progress of research and development of our products, the milestones we achieved and expect to achieve and the general market prospects and our business plan. As compared with the pre-money valuation of our Company for the Series B Investment, the valuation of our Company upon [**REDACTED**] (in terms of our expected market capitalization) is expected to increase to approximately HK$[**REDACTED**] million (based on HK$[**REDACTED**] per H Share) or HK$[**REDACTED**] million (based on HK$[**REDACTED**] per H Share), primarily due to (i) the successful commercialization of Boyounuo® (BA1101) as well as the NMPA approval obtained in February 2022 for two additional indication extrapolations of Boyounuo® (BA1101); (ii) stronger distribution capabilities as a result of the expansion of our distribution network; and (iii) the development progress for one of our Core Products, BA6101 (such as the completion of its Phase 1b clinical trial in China) as well as the seven other drug candidates in our pipeline (such as submitting IND application or obtaining IND approval).

(2) The cost per Share is calculated based on (i) the total consideration paid to the Company by the Series A Investors (or the Series B Investors); and (ii) the corresponding number of Shares held by the Series A Investors (or the Series B Investors) upon [**REDACTED**].

(3) The discount refers to the discount of the "Cost per Share paid under the Pre-[**REDACTED**] Investments" compared to the [**REDACTED**] of HK$[**REDACTED**], being the mid-point of the indicative [**REDACTED**] range set out in this document.

BACKGROUND INFORMATION OF THE PRE-[REDACTED] INVESTORS

To the best of our Directors' knowledge, information and belief, each of our Pre-[**REDACTED**] Investors, its general and limited partners (as applicable) and its ultimate beneficial owners is an Independent Third Party (save for (i) SIP Sungent, which is managed by a limited partnership whose general partner is ultimately owned by Mr. Chen Jie, one of our non-executive Directors; and (ii) Serendipity Investment, which the Luye Group has an interest in its indirect holding fund, BVCF IV, L.P., as a limited partner). The background information of our Pre-[**REDACTED**] Investors is set out below:

Name of Pre-[REDACTED] Investors	**Background**
Advantech Capital	Advantech Capital is a company incorporated in the BVI and is an affiliate of Advantech Capital II L.P. ("**Advantech Capital II**"). Advantech Capital II is a growth capital fund focusing on innovation-driven private equity investments primarily in China and its general partner is Advantech Capital Partners II Limited which is ultimately controlled by Mr. Hebert Pang Kee Chan. As of June 9, 2022, Advantech Capital II has a capital commitment of approximately US$737 million. Advantech Capital II began investing in the biopharmaceutical sector since 2018 and pursues investment opportunities in the healthcare, technology and innovation sectors, particularly companies providing innovative products, solutions or services. Within the biotech sector, Advantech Capital II's portfolio investments mainly comprise pharmaceutical companies specializing in anti-tumor or anti-inflammatory drugs and developers of innovative medical equipment or software solutions including, among others, TOT Biopharm (stock code: 1875) and Alphamab Oncology (stock code: 9966). Advantech Capital II has 52 limited partners and its largest limited partner holds approximately 17.29% interest in the partnership.

Name of Pre-[REDACTED] Investors	Background
SIP Sungent	SIP Sungent is a limited partnership established in Suzhou Industrial Park of the Jiangsu Province in the PRC whose general partner is SIP Yuansheng Private Equity Fund Investment Management Partnership (Limited Partnership) (蘇州元生私募基金管理合伙企業(有限合伙)), a limited partnership whose (i) general partner is Suzhou Industrial Park Zhinuo Business Information Consulting Co., Ltd. (蘇州工業園區智諾商務信息諮詢有限公司), a company ultimately owned by Mr. Chen Jie (陳杰), one of our non-executive Directors; and (ii) limited partners are Hainan Yuansheng Investment Partnership (Limited Partnership) (海南元生投資合伙企業(有限合伙)), a limited partnership ultimately owned by Mr. Chen Jie (陳杰), one of our non-executive Directors, and Ms. Ye Li (葉立), and which assets include companies in the innovative medicine, medical technology, diagnostic and health service industries. SIP Sungent has 47 limited partners and its largest limited partner holds approximately 9.25% interest in the partnership. SIP Sungent started investing in the biopharmaceutical sector since May 2019 and focuses on high growth life science investments. It has approximately RMB2.87 billion of assets under management, of which all 46 portfolio companies are in the biopharmaceutical sector, including Shanghai Bio-heart (stock code: 2185) and PegBio.
CCB Juyuan	CCB Juyuan is a company established in the PRC with limited liability and wholly owned by CCB International Capital Management (Tianjin) Co., Ltd. (建銀國際資本管理(天津)有限公司) ("**CCB Tianjin**"). CCB Tianjin started investing in the biopharmaceutical sector since September 2020 and has approximately RMB6 billion of assets under management, of which four portfolio companies are in the biopharmaceutical sector including Kintor Pharma (stock code: 9939) and Hinova Pharmaceuticals (Shanghai Stock Exchange stock code: 688302). CCB Juyuan is indirectly wholly owned by CCB International (Holdings) Limited (建銀國際(控股)有限公司) ("**CCBI**"). CCBI is an investment services flagship which is indirectly and wholly owned by China Construction Bank Corporation, a joint-stock company incorporated in the PRC and listed on the Main Board of the Stock Exchange (stock code: 939) and the Shanghai Stock Exchange (stock code: 601939).

Name of Pre-[REDACTED] Investors	Background
SD New Growth	SD New Growth is a company established in the PRC with a registered capital of RMB20 billion and its business includes fund investment and management of the Shandong Province Government Guidance Fund (山東省政府引導基金). SD New Growth has total assets of approximately RMB23.71 billion, of which portfolio companies in the biopharmaceutical sector include, among others, RemeGen (stock code: 9995), Cellgene Biotech and TransThera Biosciences. SD New Growth started investing in the biopharmaceutical sector since January 2016. SD New Growth is wholly owned by Shandong Provincial Department of Finance (山東省財政廳). One of our Shareholders, SD Jiazhi LP, is an investment vehicle which is owned as to 0.2% by its general partner, Shandong New Growth Drivers Private Fund Management Co., Ltd. (山東省新動能私募基金管理有限公司), and 99.8% by its limited partner, Shandong New Growth Jiayuan Pioneer Investment Partnership (Limited Partnership) (山東動能嘉元創業投資基金合伙企業(有限合伙)), a fund controlled as to approximately 93.33% by SD New Growth, all of which are ultimately owned by Shandong Provincial Department of Finance (山東省財政廳).
SZ BioResearch	SZ BioResearch is a limited partnership established in Shenzhen in the PRC which is co-managed by Wuhan Snowglobe Capital Management Co., Ltd. (武漢雪球資產管理有限公司) and Shenzhen Blue Ocean Venture Capital Investment Management Co., Ltd. (深圳藍海創業投資基金管理有限公司) ("**Blue Ocean VC**") as its general partners. Blue Ocean VC is a fund management company founded and ultimately owned by Mr. Yang Feng (楊鋒) which focuses on venture capital and private equity investments in innovative biopharmaceutical medicine, medical devices and technologies companies with high growth potential in the Greater China region. Blue Ocean VC started investing in the biopharmaceutical sector since November 2015 and has approximately RMB1.7 billion of assets under management which consists of eight portfolio companies, all of which are in the biopharmaceutical sector, including HighTide Therapeutics Inc. SZ BioResearch has seven limited partners and its largest limited partner holds approximately 36.55% interest in the partnership.

Name of Pre-[REDACTED] Investors	Background
Qianhai Equity Fund	Qianhai Equity Fund is a limited partnership established in Shenzhen Qianhai Shenzhen-Hong Kong Cooperation Zone with a current fund management scale of RMB28.5 billion. It started investing in the biopharmaceutical sector since December 2015. It has approximately RMB24 billion of assets under management, of which 48 portfolio companies are in the biopharmaceutical sector including, among others, Akesobio (stock code: 9926), Ascletis (stock code: 1672) and Shenzhen Lifetronic Technology (Shenzhen Stock Exchange stock code: 688389). It is managed by Qianhai Ark Asset Management Co., Ltd. (前海方舟資產管理有限公司) as its general partner and a company which is ultimately owned by Mr. Jin Haitao (靳海濤), which manages several investment platforms and focuses on the strategic emerging industries. Qianhai Equity Fund has 49 limited partners and its six largest limited partners all hold approximately 5.26% interest in the partnership, respectively.
Serendipity Investment	Serendipity Investment is a company incorporated with limited liability under the laws of Hong Kong. It is a wholly-owned subsidiary of Reunion Pharma, which is in turn a wholly-owned subsidiary of BVCF IV, L.P. ("**BVCF IV**"), a fund with a focus on life sciences and healthcare in China and which is managed by BVCF Management Limited ("**BVCF Management**"). BVCF Management is in turn directly owned by Dr. Yang Zhi (楊志), the founding partner of BVCF IV. BVCF IV has 17 limited partners (including the Luye Group who is interested in 12.94% equity interest in BVCF IV) and its largest limited partner holds approximately 20.07% interest in the partnership. BVCF Management manages funds that focus on international growth stage life sciences companies and has approximately US$607.3 million of assets under management. BVCF Management started managing investments in the biopharmaceutical sector since April 2013 and its portfolio companies in this sector include, among others, Yidu Tech (stock code: 2158) and Allgens Medical (Shanghai Stock Exchange stock code: 688613).

Name of Pre-[REDACTED] Investors	Background
Starr International	Starr International is a company incorporated in Hong Kong with approximately US$141.5 million of assets under management as of June 30, 2022. It is a wholly-owned subsidiary of Starr International Company, Inc. (also known as Starr International AG), a company incorporated in Switzerland which in turn is wholly owned by Starr International Foundation, a charitable foundation which is also incorporated in Switzerland. Starr International started investing in the biopharmaceutical sector since December 2015 and its portfolio companies in the healthcare industry include, among others, Gushengtang (stock code: 2273) and Jiangsu Aidea Pharmaceuticals (Shanghai Stock Exchange stock code: 688488).
Brill Aimei	Brill Aimei is a limited partnership established in Jiaozhou in the PRC whose general partner is Ningbo Yanghua Enterprise Management Consulting Investment Partnership (Limited Partnership) (寧波仰華企業管理諮詢合伙企業(有限合伙)) ("**Ningbo Yanghua**"). Ningbo Yanghua is a RMB private equity fund that invests mainly in medical and pharmaceutical, hi-tech, TMT and consumer sectors and it is ultimately controlled by Mr. Sun Peng (孫鵬), an experienced private equity investor. Ningbo Yanghua started investing in the biopharmaceutical sector since December 2020 and its portfolio companies in the biopharmaceutical sector include, among others, Gmax Biopharm. Brill Aimei has one limited partner who holds approximately 99.75% interest in the partnership and has approximately RMB60 million of assets under management, all of which are in the biopharmaceutical sector.
Yantai Blue Ocean	Yantai Blue Ocean is a company established in Yantai in the PRC and is an investment institution focusing on venture capital investment and management. It started investing in the biopharmaceutical sector since December 2020 and has approximately RMB62 million of assets under management, all of which are in the biopharmaceutical sector including, among others, Xianglong Pharmaceuticals and Gurunfeng Biotechnology. It is a wholly-owned subsidiary of Yantai Zhengda City Construction and Development Co., Ltd. (煙台市正大城市建設發展有限公司), whose ultimate beneficial owner is Yantai Laishan District State-owned Assets Administration (煙台萊山區國有資產管理局).

Name of Pre-[REDACTED] Investors	Background
GTJA Huike	GTJA Huike is a limited partnership registered in Beijing with approximately RMB205.7 million of assets under management and its general partner is Beijing GTJA Investment Management Co., Ltd. (北京高特佳資產管理有限公司), which is wholly owned by Shenzhen GTJA Investment Group Co., Ltd. (深圳市高特佳投資集團有限公司) ("**SZ GTJA Investment Group**") and the ultimate beneficial owner is Mr. Bian Zhang (卞莊). Founded in 2001, Shenzhen GTJA Investment Group focuses on investments in the medical and health industry and has established operation centers in places such as Shenzhen, Shanghai, Beijing, Nanjing and Hong Kong. It started investing in the biopharmaceutical sector in December 2020 and has invested in medical and health enterprises including, among others, VIVA Biotech (stock code: 1873), Akesobio (stock code: 9926), Henlius (stock code: 2696) and Harbour BioMed (stock code: 2142). GTJA Huike has 18 limited partners and its largest limited partner holds approximately 15.18% interest in the partnership.
Yunnan Felix	Yunnan Felix is a limited partnership established in Kunming, Yunnan Province in the PRC whose general partner and controller is Mr. Chen Shi Congde (陳石叢德), an experienced investor with a focus in hi-tech fields such as biotechnology since August 2021, of which his portfolio companies in the biotechnology sector includes, among others, HaploX. Yunnan Felix has one limited partner who holds approximately 2% interest in the partnership and has approximately RMB200 million of assets under management.

Name of Pre-[REDACTED] Investors	Background
Zhongyuan Qianhai	Zhongyuan Qianhai is a limited partnership established in Zhengdong New District of Zhengzhou in the Henan Province in the PRC whose general partner is Qianhai Ark (Zhengzhou) Venture Capital Management Enterprise (Limited Partnership) (前海方舟(鄭州)創業投資管理企業(有限合伙)), a limited partnership which is ultimately owned by Mr. Jin Haitao (靳海濤), which manages several investment platforms, covering three of the PRC's most active economic zones, namely the Greater Bay Area, Yangtze River Delta and Yellow and Bohai Sea Rim. Zhongyuan Qianhai has 20 limited partners and its largest limited partner holds approximately 17.73% interest in the partnership. It started investing in the biopharmaceutical sector in December 2019 and has approximately RMB5.14 billion of assets under management, of which 18 portfolio companies are in the biopharmaceutical sector, including, among others, Shanghai Bio-heart (stock code: 2185), Guangzhou Huayin Health Medical Group and Bluepha.
Brill Luoyi	Brill Luoyi is a limited partnership established in Ningbo Free Trade Port District in the PRC whose general partner is Ningbo Yanghua. Ningbo Yanghua is a RMB private equity fund that invests mainly in medical and pharmaceutical, hi-tech, TMT and consumer sectors and it is ultimately controlled by Mr. Sun Peng (孫鵬), an experienced private equity investor. Ningbo Yanghua started investing in the biopharmaceutical sector since December 2020 and its portfolio companies in the biopharmaceutical sector include, among others, Gmax Biopharm. Brill Luoyi has two limited partners and its largest limited partner holds 50% interest in the partnership. Brill Luoyi has approximately RMB55 million of assets under management, all of which are in the biopharmaceutical sector.
Qianhai Weiyang	Qianhai Weiyang is a limited partnership established in Shenzhen Qianhai Shenzhen Cooperation Zone of the PRC whose general partner and managing partner is Mr. Su Junhang (蘇俊航) ("**Mr. Su**"). It is funded by Mr. Su, Ms. Zhang Xuemei (張雪美) and Ms. Chen Siling (陳思伶). Qianhai Weiyang has two limited partners and they hold 10% interest in the partnership, respectively. Qianhai Weiyang started investing mainly in, among others, the biopharmaceutical sector since December 2020 and has approximately RMB20 million of assets under management.

Name of Pre-[REDACTED] Investors	Background
Yantai Bohui	Yantai Bohui is a limited partnership established in Yantai Area of Shandong Pilot Free Trade Zone in the PRC and is principally engaged in equity investment business. It started investing in the biopharmaceutical sector since January 2021 and has approximately RMB20 million of assets under management, all of which are in the biopharmaceutical sector. Its general partner is Mr. Zhang Jixiang (張繼祥) ("**Mr. Zhang**") who is the president of the business department of Yantai Guotai Chengfeng Asset Management Co., Ltd. (煙台國泰誠豐資產管理有限公司) ("**Yantai Guotai**"). Yantai Bohui has one limited partner who holds approximately 99.99% interest in the partnership. It is funded by Yantai Guotai and Mr. Zhang and its beneficial owner is Yantai State-owned Assets Supervision and Administration Commission (煙台市國資委).
Hainan Wensen	Hainan Wensen is a limited partnership established in Yantai, Shandong Province of the PRC whose general and managing partner is Mr. Tan Sen (譚森) ("**Mr. Tan**"), the founder and executive director of Weihai Shengtaiyuan Foods Co., Ltd. ("**Shengtaiyuan Foods**"). Hainan Wensen has one limited partner who holds 80% interest in the partnership. It is beneficially owned and funded by Mr. Tan and Ms. Song Wenxia (宋文霞), a retired financial manager who previously served at Weihai Kunyu Hotel Co., Ltd. (威海昆嵛酒店有限公司). It started investing in the biopharmaceutical sector since January 2021 and has approximately RMB18 million of assets under management, all of which are in the biopharmaceutical sector.

Name of Pre-[REDACTED] Investors	Background
Yantai Innovative	Yantai Innovative is a limited partnership established in the Yantai Hi-tech Zone of Shandong Province in the PRC, whose general partner and manager is Yantai Financial Investment Holdings Co., Ltd. (煙台市財金投資控股有限公司) ("**YFIH**") which is in turn wholly owned by Yantai Financial Development Investment Group Co., Ltd. (煙台市財金發展投資集團有限公司) whose ultimate beneficial owner is Yantai Finance Administration (煙台市財政局). YFIH started investing in the biopharmaceutical sector since June 2018 and has approximately RMB1.8 billion of assets under management, of which portfolio companies in the biopharmaceutical sector include, among others, MabPlex International. Yantai Innovative has one limited partner who holds approximately 67.63% interest in the partnership, Yantai Financial New Growth Drivers Fund Management Co., Ltd., (煙台市財金新動能基金管理有限公司), whose ultimate beneficial owner is Yantai Finance Administration (煙台市財政局). Yantai Innovative is an investment institution focusing on supporting technology innovation enterprises in, among others, the medical and healthcare field and has approximately RMB86.5 million of assets under management as of September 22, 2022.
Nanjing Ruiyuan	Nanjing Ruiyuan is a limited partnership established in Nanjing in the PRC by four individual partners who are all senior management members of Hencer Pharma, namely Ms. Yang Jie (楊潔) ("**Ms. Yang**"), Mr. Xiong Shoujun (熊守軍), Ms. Cha Jing (查晶) and Ms. Wei Yanqiong (衛彥瓊). The four partners have been working in the pharmaceutical industry for over 20 years with extensive experiences in the pharmaceutical and health industry as well as the pharmaceutical industry chain. Nanjing Ruiyuan's general partner is Ms. Yang and it has three limited partners who all hold 20% interest in the partnership, respectively. Nanjing Ruiyuan has approximately RMB45 million of assets under management and started investing in the biopharmaceutical sector since 2020.

Name of Pre-[REDACTED] Investors	Background
SZ Xingrui	SZ Xingrui is a limited partnership established in Shenzhen in the PRC whose general partner is Shenzhen Hangrui Management Consulting Co., Ltd. (深圳市航睿管理諮詢有限公司) ("**SZ Hangrui**"), a company with approximately RMB350 million of assets under management and investments in seven portfolio companies, of which four are in the biopharmaceutical and healthcare sectors. SZ Hangrui's ultimate beneficial owners are Mr. Du Yongyue (杜踴躍) and Ms. Wu Yao (吳瑤). SZ Xingrui has two limited partners and its largest limited partner holds 65% interest in the partnership. SZ Xingrui started investing in the biopharmaceutical sector in December 2020 and invests mainly in hi-tech, new energy, medical and healthcare sectors and has approximately RMB20 million of assets under management.
Asian Alliance	Asian Alliance is a company incorporated with limited liability under the laws of Hong Kong and is a wholly-owned subsidiary of Asia Pharma. Asia Pharma is a wholly-owned subsidiary of BVCF Coinvest A, L.P., which is managed by BVCF Management. BVCF Management is in turn directly owned by Dr. Yang Zhi (楊志), the founding partner of BVCF IV, a fund with a focus on life sciences and healthcare in China. BVCF Management manages funds that focus on international growth stage life sciences companies and has approximately US$607.3 million of assets under management. BVCF Management started managing investments in the biopharmaceutical sector since April 2013 and its portfolio companies in this sector includes, among others, Yidu Tech (stock code: 2158) and Allgens Medical (Shanghai Stock Exchange stock code: 688613).

Among the Pre-[**REDACTED**] Investors set out above, each of Advantech Capital, CCB Juyuan, SD Jiazhi LP, SZ BioResearch, Qianhai Equity Fund, Starr International, Zhongyuan Qianhai and Yantai Innovative is an established institutional investor and falls within the definition of a "Sophisticated Investor" under Guidance Letter HKEX-GL92-18.

SPECIAL RIGHTS GRANTED TO THE PRE-[REDACTED] INVESTORS

Under the respective investment agreements entered into between the Pre-**[REDACTED]** Investors and our Company and the shareholders' agreement entered into among our Company and its then Shareholders, the Pre-**[REDACTED]** Investors were granted certain special rights, including but not limited to information rights, pre-emptive rights, director nomination rights, anti-dilution rights and veto rights for certain corporate actions. All of these special rights granted to the Pre-**[REDACTED]** Investors will be terminated and cease to have any effect upon **[REDACTED]**.

[REDACTED]

[REDACTED], **[REDACTED]** and **[REDACTED]** Shares held by our ESOP Entities (namely, Yantai Bolian, Yantai Bosheng and Yantai Bofa, whose general partner is Ms. Li Li, one of our non-executive Directors), representing **[REDACTED]**%, **[REDACTED]**% and **[REDACTED]**% of the total share capital of our Company upon **[REDACTED]** respectively, will not be considered as part of the **[REDACTED]** of our Company.

Save for those Shares held by SIP Sungent (i.e. **[REDACTED]** Shares), all of the Shares held by the Pre-**[REDACTED]** Investors (i.e. **[REDACTED]** Shares) will be counted towards the **[REDACTED]** for the purpose of Rule 8.08 of the Listing Rules. Upon **[REDACTED]**, **[REDACTED]** Shares representing approximately **[REDACTED]**% of the total share capital of our Company will be considered as part of the **[REDACTED]** of our Company. Taking into account the post-money valuation of our Company upon completion of the Pre-**[REDACTED]** Investments, we expect that over 25% of our Company's total issued Shares with a market capitalization of substantially over HK$375 million will be held by the public upon completion of the **[REDACTED]** in accordance with Rules 8.08(1)(a) and 18A.07, respectively, of the Listing Rules.

COMPLIANCE WITH INTERIM GUIDANCE AND GUIDANCE LETTERS

On the basis that (i) the consideration for each of the Pre-**[REDACTED]** Investments was settled at least 28 clear days prior to the date of the first submission of the **[REDACTED]** to the Stock Exchange and (ii) special rights granted by our Company to the Pre-**[REDACTED]** Investors will not survive after **[REDACTED]**, the Joint Sponsors are of the view that the Pre-**[REDACTED]** Investments are in compliance with the Interim Guidance on **[REDACTED]** Investments (HKEX-GL29-12) and the Guidance on Pre-**[REDACTED]** Investments (HKEX-GL43-12).

OVERVIEW

We are an integrated biopharmaceutical company committed to developing, manufacturing and commercializing high quality biologics across various therapeutic areas in China and overseas. Since our inception in 2013, we have fostered multiple key elements we believe will help us capture the strong market opportunity in biologics, including:

(i) a management team with extensive industry experience and market insight that has pushed forward our strategic plans including successfully bringing Boyounuo® (BA1101) to market in China in May 2021;

(ii) a robust and risk-balanced portfolio, which brings us clear short-term commercial visibility and allows us to pursue long-term sustainable growth;

(iii) an integrated biopharmaceutical platform; and

(iv) collaboration with various resourceful business partners, laying the foundation for our strong commercialization capability.

We focus our platform, people and partnerships on offering access to innovative biologics as well as affordable biosimilars. To date, we have commercialized Boyounuo® (BA1101) and recorded a revenue of RMB158.7 million in about eight months in 2021 and RMB220.7 million for the six months ended June 30, 2022, which demonstrated our capability to bring our biologics portfolio to market.

We independently developed all of our portfolio in-house, which focuses on popular key therapeutic areas including oncology, metabolism, autoimmunity and ophthalmology, which entail significant unmet market demand and potential in China and globally due to their immense market sizes. Our portfolio brings us clear short-term commercial visibility and allows us to pursue long-term sustainable growth. As of the Latest Practicable Date we had a commercialized product and a total of 13 drug candidates, consisting of eight innovative antibody candidates and five biosimilar candidates. 11 of our drug candidates had entered or completed clinical trials or received the IND approvals from the CDE, comprising one drug candidate with BLA approved, three in Phase 3 clinical trial, one in Phase 2 clinical trial, four in Phase 1 clinical trial, and two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phases 1 and 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®.

We boast our integrated biopharmaceutical platform with proprietary R&D technology. Our integrated platform and deep experience and capabilities built thereon extend to the entire biologics value chain and have provided us with substantial control over quality and resource allocation. Furthermore, we established proprietary BA-huMab® platform, phage display technology platform, bispecific T-cell engager technology platform and ADC technology platform which we believe provide us with great technological support. Our R&D teams based in Yantai and Nanjing in China and Boston in the United States have rich experience and strong track records in drug discovery and development, including having developed extensive experience in areas of antibody discovery, cell line development, upstream and downstream process development, analytical and bio-analytical method development, technology transfer, pilot and commercial scale production.

We have strong CMC capability which is the backbone to the high quality and cost efficiencies we have maintained throughout the process of our drug development and commercial production, especially in cell line development, upstream and downstream process development, analytical and bio-analytical method development as well as technology transfer. In addition, we have a sizable pilot and commercial production site located in Yantai, China which has a total GFA of approximately 33,504.1 sq.m. and houses a number of production lines with a capacity of 1,700L for pilot production and 8,000L for commercial production, as well as two formulation filling lines for both pilot and commercial production, consisting of (i) the vial filling formulation line with a designed production capacity of 2.5 million vials per annum, and (ii) the pre-filled product formulation line of 3.5 million pre-filled syringes per annum. We employ a robust quality management system for the Yantai Site that meets various quality standards such as GMP set by the relevant regulatory authorities of China and the EU and had passed a number of audits in China and the EU.

Our collaboration with various resourceful business partners lays the foundation for our strong commercialization capability. We had an extensive distribution network of 160 distributors as of June 30, 2022, penetrating selected regions and reaching more than 1,100 target hospitals and institutions in China. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China. We also collaborate with experienced third-party promoters which effectively publicize and maximize the market potential of our products. On May 26, 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, regarding the promotion rights to Boyounuo® (BA1101) for a term of five years, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. On October 28, 2020 we entered into an agreement with OcuMension, as amended by a supplemental agreement dated May 31, 2021, regarding the product development cooperation and promotion and commercialization of BA9101 in China for a term of 10 years, under which we granted OcuMension certain exclusive rights to promote and commercialize BA9101 in China. Our strong commercialization capability is further bolstered by a dedicated in-house sales and marketing team with extensive industry experience.

The following table summarizes our Commercialized Product and drug candidate pipeline under development in China and worldwide across various therapeutic areas as of the Latest Practicable Date:

	Therapeutic area	Product (reference drug)	Target	Indication	Commercial rights	Clinical trial region	Pre-clinical	IND	Phase 1	Phase 2[10]	Phase 3	BLA filed	BLA approved
Innovative Antibody Portfolio	Infectious Disease	★ LY-CovMab[1]	SARS-CoV-2 spike protein	COVID-19	Worldwide	China							
		BA-CovMab	SARS-CoV-2 spike protein	COVID-19	Worldwide	China							
	Oncology	BA1105	Claudin 18.2 (ADCC)	Advanced gastric cancer, metastatic pancreatic cancer, and adenocarcinoma of the esophagogastric junction	Worldwide	China							
		BA1301	Claudin 18.2 ADC	Gastric cancer, pancreatic cancer, and esophageal cancer	Worldwide	China							
		BA1201	PD-L1/TGF-β	SCLC, NSCLC, cervical cancer, urothelial carcinoma, and advanced gastrointestinal tumors	Worldwide	China							
		BA1202	CEA/CD3	CRC, pancreatic duct adenocarcinoma, etc.	Worldwide	China							
		BA1106	CD25	Solid tumors	Worldwide	China							
	Autoimmunity	BA2101	IL4R	Atopic dermatitis, asthma, sinusitis, pruritus, urticaria, etc.	Worldwide	China							
Biosimilar Portfolio	Oncology	Boyounuo®* (BA1101, Avastin® biosimilar)[2]	VEGF	mCRC, advanced metastatic or recurrent NSCLC, recurrent glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer, and cervical cancer	Worldwide	China							
		★ BA1102 (Xgeva® biosimilar)[3]	RANKL	Bone metastases from solid tumors, and GCTB	Worldwide	China							
						Overseas							
		BA1104 (Opdivo® biosimilar)[4]	PD-1	Melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma	Worldwide	China							
						Overseas							
	Metabolism	★ BA6101 (Prolia® biosimilar)[5]	RANKL	Osteoporosis[6]	Worldwide	China							
						Overseas							
		BA5101 (Trulicity® biosimilar)[7]	GLP-1	Type 2 diabetes	Worldwide	China[11]							
						Overseas							
	Ophthalmology	BA9101 (Eylea® biosimilar)[8] [9]	VEGF	wAMD, RVO, DME, and DR	Worldwide[9]	China							
						Overseas							

Notes:

★ Denotes our Core Products.

* Denotes our Commercialized Product.

(1) We expect to submit the BLA of LY-CovMab in 2024. For more details, see "Business — Our innovative antibody portfolio — Our Core Product: LY-CovMab".

(2) The generic name of Boyounuo® (BA1101) is bevacizumab. We entered into an agreement with AstraZeneca China with respect to Boyounuo® (BA1101) on May 26, 2021, as amended by a supplemental agreement dated March 7, 2022, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. For more details, see "— Our biosimilar portfolio — Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®)" in this section.

(3) The generic name of BA1102 is denosumab. We expect to submit the BLA of BA1102 in the first quarter of 2023 in China. The results of the Phase 1 clinical trial in the EU are expected to become available in the second half of 2023. Although BA1102 and BA6101 contain the same active agent, denosumab, they were developed as separate product candidates rather than expansion of indications of each other. The generic name of BA1102 is denosumab. For more details, see "— Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)" in this section.

(4) The generic name of BA1104 is nivolumab. For more details, see "Business — Our biosimilar portfolio — BA1104 (a biosimilar to Opdivo®)".

(5) The generic name of BA6101 is denosumab. We received the regulatory approval to commence commercialization in November 2022 in China. It is also currently under Phase 1 clinical trial in the EU, the results of which are expected to become available in the second half of 2023. For more details, see "— Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)" in this section.

(6) Treatments of various osteoporosis consist of (i) treatment of postmenopausal women with osteoporosis at high risk for fracture, (ii) treatment to increase bone mass in men with osteoporosis at high risk for fracture, (iii) treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, (iv) treatment to increase bone mass in men at high risk for fracturereceiving androgen deprivation therapy for nonmetastatic prostate cancer and (v) treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

(7) The generic name of BA5101 is dulaglutide. For more details, see "Business — Our biosimilar portfolio — BA5101 (a biosimilar to Trulicity®)".

(8) The generic name of BA9101 is aflibercept. We expect to submit the BLA of BA9101 in the first half of 2024 in China. For more details, see "— Our biosimilar portfolio — BA9101 aflibercept intraocular injection (a biosimilar to Eylea®)" in this section.

(9) We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, pursuant to which we are responsible for conducting certain initial stages of the Phase 3 clinical trial and commercial production as well as submitting the BLA of BA9101 and OcuMension is responsible for completing the rest of Phase 3 clinical trial and promoting and commercializing BA9101 in China. The term of the agreement ends on the tenth anniversary following the date of first delivery of BA9101 after marketing approval has been obtained. For more details, see "— Commercialization, sales, marketing and distribution — R&D partner and promoter" in this section.

(10) In the PRC, the NMPA has issued a number of guidelines encouraging biosimilar research and development, including the Biosimilar Guidelines, which set out the regulatory framework for registering and evaluating new biosimilar candidates. In general, the NMPA requires that biosimilars match the relevant reference drugs in terms of indications, usage guidelines and safety information. In addition, the biosimilar approval pathway is established based on the scientific objective of proving that there are no clinically-meaningful differences in the safety and efficacy of biosimilars when compared to the reference drug. Based on this principle, there is generally no need to conduct a Phase 2 clinical trial for biosimilars since the proper dose assuring safety and efficacy has already been determined for the reference product.

Our seasoned management team has solid knowledge and deep industry experience, and some of whom have extensive experience in leading from drug development towards commercialization. Specifically, Ms. Jiang Hua, our chairlady and chief executive officer, has over 23 years of experience in the pharmaceutical industry in China. Dr. Dou Changlin, our president of R&D and chief operating officer, has over 24 years of experience in the pharmaceutical industry, including biopharmaceutical R&D, manufacturing and quality management. He has accumulated solid knowledge and deep industry experience by working in a number of reputable companies, including being a group leader at Genentech, Invitrogen Corporation and Cellular Dynamics International, a chief technical officer at A-Bio Pharma Pte. Ltd and a director of biotechnology at the Luye Group. Under the leadership of our management team, we have assembled a high-caliber team of professionals working closely with each other towards our vision.

Subsequent to the successful launch of Boyounuo® (BA1101) in May 2021, we further made several achievements including (i) obtaining the NMPA approvals to extrapolate its indications to recurrent glioblastoma in July 2021 and epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in February 2022, which further broaden the product's market potential, and (ii) publishing two papers in *Cancer Communications* and *Expert Opinion on Biological Therapy* in May and December 2021, respectively, covering the clinical trial comparing its efficacy and safety with that of Avastin® in first-line treatment of Chinese patients with advanced metastatic or recurrent NSCLC, as well as the study comparing its pharmacokinetic (PK) profiles, safety and immunogenicity with those of Avastin® in healthy Chinese males.

During the Track Record Period, we recorded a revenue of nil in 2020 and RMB158.7 million in 2021, and RMB12.1 million and RMB220.7 million for the six months ended June 30, 2021 and 2022, respectively, which reflects our sales of Boyounuo® (BA1101) since its launch in May 2021. We recorded gross profit of nil and RMB106.5 million for the years ended December 31, 2020 and 2021, respectively, and RMB8.8 million and RMB147.3 million for the six months ended June 30, 2021 and 2022, respectively. We recorded net loss of RMB240.5 million and RMB225.4 million for the years ended December 31, 2020 and 2021, respectively, and RMB127.9 million and RMB153.3 million for the six months ended June 30, 2021 and 2022, respectively.

OUR STRENGTHS

We believe the following strengths have contributed towards our success and differentiate us from other biopharmaceutical companies.

Robust and risk-balanced portfolio that brings us clear short-term commercial visibility and fuels long-term sustainable growth

We, through years of efforts and dedication, have incubated a robust and risk-balanced portfolio, which brings us clear short-term commercial visibility and allows us to pursue long-term sustainable growth. Specifically, our portfolio, including one commercialized drug and 13 drug candidates, focuses on popular key therapeutic areas including oncology, metabolism, autoimmunity and ophthalmology, which entail significant unmet market demand and potential in China and overseas. For example, our

current drug candidates cover, among others, the treatment of lung, gastric, colorectal, liver and esophageal cancers, representing five out of the top 10 cancers in China and globally in 2021, according to the Frost & Sullivan Report. The size of global and China patient groups with medical demand in key therapeutic areas of oncology, metabolism, autoimmunity and ophthalmology, has exceeded 2 billion and over 250 million of patients, respectively, in 2021. The global drug market size of these key therapeutic areas is also immense and growing steadily, reaching US$181.7 billion, US$239.5 billion, US$127.7 billion and US$36.0 billion, respectively, for 2021, and is expected to increase to US$484.5 billion, US$359.8 billion, US$176.0 billion and US$73.7 billion, respectively, for 2030, representing a respective CAGR of 11.5%, 4.6%, 3.6% and 8.3% between 2021 and 2030, according to the Frost & Sullivan Report. Similarly, in China the drug market size of the aforementioned key therapeutic areas was RMB231.1 billion, RMB99.9 billion, RMB19.3 billion and RMB20.4 billion, respectively, for 2021, and is expected to increase to RMB651.3 billion, RMB188.5 billion, RMB148.8 billion and RMB99.2 billion, respectively, for 2030, representing a respective CAGR of 12.2%, 7.3%, 25.5% and 19.2% between 2021 and 2030, according to the Frost & Sullivan Report. The capability and flexibility for combination therapies of our drug candidates are expected to further broaden their market prospects.

Led by our first commercialized drug, Boyounuo® (BA1101), our portfolio provides a clear path for both short-term and long-term commercialization. We launched Boyounuo® (BA1101) in May 2021 in China which is well received in the market evidenced by its sales revenue of RMB158.7 million in about eight months in 2021, and RMB220.7 million for the six months ended June 30, 2022, becoming one of the few Avastin® (bevacizumab) biosimilars in China reaching sales revenue of more than RMB150.0 million within a year since their debut according to the Frost & Sullivan Report. Apart from our Commercialized Product, as of the Latest Practicable Date we had a total of 13 drug candidates, 11 of which had entered or completed clinical trials or received the IND approvals from the CDE, comprising one drug candidate with BLA approved, three in Phase 3 clinical trial, one in Phase 2 clinical trial, four in Phase 1 clinical trial, and two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phases 1 and 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®.

Our robust and risk-balanced pipeline includes eight innovative antibody candidates and five biosimilar candidates. We strategically develop our innovative antibody candidates to focus on novel formulations with significant market potential. For instance, our BA1105 targets a larger applicable patients pool and we believe it is a potential best-in-class drug candidate for the treatment of gastric cancer with Claudin 18.2 expression because it demonstrates stronger anti-tumor activities in *in vitro* and *in vivo* models compared to other clinical-stage drug candidates with same target for the treatment of gastric cancer. Our BA1106, based on its pre-clinical data, shows strong efficacy for both early-stage and late-stage tumors, and it demonstrates a good synergetic effect when used in combination with an anti-PD-1 antibody and inhibits

immunosuppression in tumor microenvironment without blocking the IL-2 signaling pathway. Our LY-CovMab, an innovative antiviral drug candidate for the treatment of COVID-19, is currently under Phase 2 clinical trial.

Besides our innovative antibody portfolio, we also have an advanced biosimilar portfolio with an early-mover advantage and with near-term commercialization potential in China. As of the Latest Practicable Date, in addition to Boyounuo® (BA1101) that had been commercialized, we had a pipeline of five biosimilar candidates, including three potential first-wave-to-market drug candidates, three of which were in Phase 3 clinical trial and one had its regulatory approval to commence commercialization obtained in China. We believe our potential first-wave-to-market biosimilar candidates can seize the early-mover advantage on market share and pricing power in China and generate near-term cash flows to fund the continued development of our drug pipelines.

We independently developed our first commercialized product, Boyounuo® (BA1101), an anti-VEGF humanized monoclonal antibody injection and an Avastin® (bevacizumab) biosimilar. In April 2021, Boyounuo® (BA1101) was approved by the NMPA for the treatment of advanced metastatic or recurrent NSCLC and mCRC, being the third NMPA-approved Avastin® (bevacizumab) biosimilar in China. Lung and colorectal cancers were two of the largest indications by incidence and two of the top five cancers by mortality in China and globally in 2020 according to the Frost & Sullivan Report. The NMPA further approved Boyounuo® (BA1101) for the treatment of recurrent glioblastoma in July 2021 and epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in February 2022. We believe Boyounuo® (BA1101) has the potential to extrapolate its indications further to HCC and other major cancers, unlocking huge market potential. The significant market potential of Boyounuo® (BA1101) can be demonstrated by the over RMB5 billion sales of bevacizumab in China, the generic name for Boyounuo® (BA1101), in 2020, according to the Frost & Sullivan Report. Leveraging the significant market size of bevacizumab, our early-mover advantage in China and a broad indication coverage, we believe Boyounuo® (BA1101) is well positioned to compete in the market for bevacizumab and gain a leading market share in China.

Our advanced biosimilar portfolio has a number of near commercial-stage drug candidates. For example, BA6101 is a potential first-to-market biosimilar drug in China targeting postmenopausal women with osteoporosis at high risk for fracture, the regulatory approval to commence commercialization of which had been received in November 2022. It is also currently under Phase 1 clinical trial in the EU. BA1102 is potentially one of the three first-to-market biosimilar drugs in China targeting bone metastases from solid tumors and GCTB, and is currently under Phase 3 clinical trial in China, and we expect to submit its BLA in the second half 2022 in China. BA9101 is potentially one of the first-to-market biosimilars in China targeting wAMD and DME, and is currently under Phase 3 clinical trial in China, and we expect to submit its BLA in the first half of 2024 in China.

We purposefully structure our portfolio to achieve a risk-balanced profile. On the one hand, we put a strategic emphasis on key therapeutic areas in China in terms of market potential and at the same time develop multiple drug candidates with various antibody targets. We believe the differentiation provides us with greater therapeutic

flexibility, diversifies our products' risk profile, and enables us to serve broader groups of patients and thus achieve higher commercial value. We also strategically select antibody targets covering both mature targets with high drug-ability (such as PD-1, VEGF and RANKL) and relatively new targets and new technologies that are expected to have great market potential (such as ADC, Claudin 18.2 and CD25).

Integrated biopharmaceutical platform with proprietary R&D technology and validated outstanding drug development capability

At the heart of our competitive strength is our integrated biopharmaceutical platform. It is empowered by advanced R&D technologies as well as strong manufacturing and commercialization capabilities with a focus on therapeutic areas of oncology, metabolism, autoimmunity and ophthalmology. Our integrated platform and deep experience and capabilities built thereon extend to the entire biologics value chain, ranging from antibody discovery, cell line development, upstream and downstream process development, analytical development, technology transfer, and pilot and commercial scale production to sales and marketing. Our integrated platform has provided us with substantial control over quality and resource allocation, and enables us to achieve operational and process efficiencies across R&D and manufacturing, and to rapidly, flexibly and efficiently pursue new drug development opportunities to advance a broad portfolio. For example, we can efficiently screen antibodies, develop manufacturing processes, conduct clinical trials, conduct process characterization, process validation and manufacture products, and redeploy resources to prioritize our most promising projects. The commercialization of Boyounuo® (BA1101) also demonstrates our strong execution ability via our end-to-end biopharma platform to push forward the development of drug candidates from discovery to commercialization in less than five years from IND approval to commercialization. We believe we will continue to benefit from the scalability and cost efficiency of our integrated platform when we expand our manufacturing capacity and sales and marketing team for Boyounuo® (BA1101) and other drug candidates moving into commercial stage in the future.

We have a fully-fledged proprietary R&D technology platform focusing on antibody discovery and drug development. We have R&D teams and facilities located in Yantai and Nanjing in China and Boston in the United States, with rich experience and strong track records in drug discovery and development. In terms of technology, we boast proprietary BA-huMab® platform, phage display technology platform, bispecific T-cell engager technology platform and ADC technology platform which we believe provide us with great technological support.

We utilize our BA-huMab® and phage display technology platforms during antibody discovery. Our human antibody transgenic mice developed under the BA-huMab® platform contains 30 human antibody κ light chain variable region genes, 110 human antibody heavy chain variable region genes (IgM&IgG1). It can directly generate human antibodies without need for humanization, which significantly accelerates antibody discovery process and decreases immunogenicity risk. BA-huMab® is able to elicit an immune response quickly and produces a high antibody titer after immunization. We have successfully identified potential candidates of over 10 targets through the human antibody transgenic mice BA-huMab®, with high affinity and high specificity. For

example, LY-CovMab, BA1105, BA1106 and BA1201 were developed under the BA-huMab® platform. Our phage display technology platform offers a mature and advanced phage library construction technology. Quality of phage libraries is strictly controlled with the capacity of immunized libraries larger than 10^9 and sequence accuracy rate higher than 95%.

Our bispecific T-cell engager technology platform can effectively eliminate tumor cells expressing target proteins, increase the infiltration of immune cells into tumor tissues, and stimulate cold tumors turning into hot tumors. Our studies revealed that our bispecific T-cell engager format exhibits high avidity with tumor target antigen by bivalent binding to achieve better drug efficacy, and low affinity with T-cells by monovalent binding to lower toxicity. Meanwhile, our bispecific T-cell engager technology platform further reduces CD3 binding affinity, therefore significantly reduces the risk of CRS. For example, BA1202 was developed under the bispecific T-cell engager technology platform. We have established the ADC technology platform covering the whole process of ADC discovery and development. It enables us to discover and develop ADC candidates efficiently and quickly, which contributes to the diversification of our platform and portfolio. For example, BA1301 was developed under the ADC technology platform.

These technologies together promote significant synergies by allowing us to, among others, carry out integrated antibody discovery, cell line development, upstream and downstream process development, analytical development, technology transfer, and pilot and commercial scale production capability. Underpinned by our strong R&D capability, we have published 10 research papers in world-renowned academic journals including *Scientific Reports of Nature*, *Antibody Therapeutics*, and *Cancer Communications*, introducing our research breakthroughs on some of our drug candidates.

Our high caliber R&D team has outstanding execution capability in drug development with a proven track record. As of June 30, 2022, our R&D team consisted of 253 experienced employees covering biopharmaceutical discovery research, biotechnology research, biopharmaceutical analysis research, biological activity research, non-clinical research, pilot process research, clinical research, regulatory affairs, project management and intellectual property and other R&D functions, most of whom had R&D and clinical experience of more than six years. Our experienced clinical development team is in charge of formulating clinical strategies and designing appropriate clinical trials to efficiently and expeditiously move forward R&D programs. As testament to our R&D team's execution capability, for Boyounuo® (BA1101) we spent only 26, 12 and one month(s), respectively, (i) from submitting the IND application to initiating clinical trials, (ii) from submitting the BLA to receiving the NMPA approval and (iii) from receiving the NMPA approval to product launch, faster than the respective industry average of 29 months, 14.6 months and 2.3 months, respectively, according to the Frost & Sullivan Report.

Strong CMC capability supporting drug development and enabling enhanced cost efficiencies in commercial-scale production

We take pride in our strong CMC capability which is the backbone of the high quality and cost efficiency we have maintained throughout the process of our drug development and commercial production, especially in cell line development, upstream and downstream process development, analytical and bio-analytical method development as well as technology transfer. Our CMC function establishes practical qualitative and quantitative standards for us to maintain product quality and effectively progresses drug discovery to actual manufacturing.

We have a sizable pilot and commercial production site located in Yantai, China. We employ a robust quality management system for the Yantai Site that meets various quality standards such as GMP set by the relevant regulatory authorities of China and the EU and has passed a number of audits in China and the EU. Our Yantai Site, having a total GFA of approximately 33,504.1 sq.m., houses a number of production lines with a total capacity of 1,700L for pilot production and 8,000L for commercial production, as well as two formulation filling lines for both pilot and commercial production, consisting of (i) the vial filling formulation line with a designed production capacity of 2.5 million vials per annum, and (ii) the pre-filled product formulation line of 3.5 million pre-filled syringes per annum. We plan to increase the capacity of our Yantai Site by an additional 2,000L for pilot production and another 12,000L for commercial production by 2024. With the growing production capability, we expect to generally keep production in house to ensure quality and efficiency. Our production is managed by a strong manufacturing team, which as of June 30, 2022 had a total of 305 employees.

Besides production capacity, our proprietary manufacturing capability, such as perfusion culture and fed-batch culture, provides flexibility and improves the throughput and production efficiency. Our Yantai Site is also highly versatile, adaptable to manufacturing drugs targeting different antibodies, and is capable of producing various formulations. To further improve production cost efficiency, we utilize digital management in production.

Our strong CMC capability accumulated through years of effort shortens drug development time and enables speed-to-market. We believe such capability is a formidable barrier to competitors and has paved the way for our early-mover advantage.

Well-established commercialization capability enabling speed-to-market with a proven track record

Leveraging our well-established and proven commercialization capability backed by marketing strategies implemented by dedicated marketing teams, we believe we are well positioned to achieve speed-to-market and the rapid ramp-up of product sales. Our collaboration with various resourceful business partners lays the foundation for our strong commercialization capability. We had an extensive distribution network of 160 distributors as of June 30, 2022, penetrating selected regions and reaching more than 1,100 target hospitals and institutions in China, and we plan to expand our product exposure to more hospitals by increasing our distribution network. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China.

Our collaboration with experienced third-party promoters effectively publicizes and maximizes the market potential of our products. For example, on May 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, regarding the promotion rights to Boyounuo® (BA1101) for a term of five years, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain cities and counties of various provinces and autonomous regions in China. We have seen significant progress delivered by our collaboration with AstraZeneca China, which has contributed its years of broad market coverage and channel development in China. Through joint efforts, as of the Latest Practicable Date, Boyounuo® (BA1101) was eligible for local medical insurance coverage in 30 provinces, autonomous regions and municipalities in China. Apart from our success in the commercialization of our launched product, we also pay close attention to identify and maximize early commercialization opportunities of advanced drug candidates. For example, on October 28, 2020 we entered into an agreement with OcuMension, as amended by a supplemental agreement dated May 31, 2021, regarding the product development cooperation and promotion and commercialization of BA9101 in China for a term of 10 years, under which we granted OcuMension certain exclusive rights to promote and commercialize BA9101 in China. Our strong commercialization capability is further bolstered by a dedicated in-house sales and marketing team with extensive industry experience. On the one hand, it manages market data analysis, market forecast analysis for product candidates in our pipeline and product promotion and marketing. On the other, it leads and participates in negotiations with government agencies and hospitals to facilitate our product to become eligible for local medical insurance coverage in China, accepted by hospitals and added to procurement lists. We have also collaborated with several leading and influential PIs on our clinical trials, paving the way for pre-launch market education. The leading PIs for our clinical trials are also renowned KOLs nationwide. We believe they are able to help us increase clinical acceptance of our drug candidates among doctors and accelerate market penetration.

We have a proven track record in the successful launch of Boyounuo® (BA1101), which is indicative of our outstanding commercialization capability and readiness to execute future commercialization plans. Our Boyounuo® (BA1101), launched in May 2021, is the third NMPA-approved Avastin® (bevacizumab) biosimilar in China and quickly generated a revenue of RMB158.7 million in about eight months in 2021 following its launch and RMB220.7 million for the six months ended June 30, 2022, becoming one of the few Avastin® (bevacizumab) biosimilar in China reaching sales revenue more than RMB150.0 million within a year since their launch. Boyounuo® (BA1101) first received the NRDL payment code within three months after launch, and subsequently become eligible for local medical insurance coverage in 30 provinces, autonomous regions and municipalities in China as of Latest Practicable Date. We believe the obtainment of NRDL payment code for Boyounuo® (BA1101) will further increase its market share and penetration.

Management team with extensive industry experience and market insight, supported by reputable investors

We boast a seasoned management team who lead us to navigate the competitive and complex biopharmaceutical industry. They have solid knowledge and deep industry experience, and some of whom have extensive experience in leading from drug development towards commercialization.

Ms. Jiang Hua, our chairlady and chief executive officer, has over 23 years of experience in the pharmaceutical industry in China. Prior to joining our Group, from September 1998 to September 2020, she worked at Luye Group with her last position as vice president, where she was primarily responsible for the Luye Group's investment, strategy and business development and investor relations management.

Dr. Dou Changlin, our president of R&D and chief operating officer, has over 24 years of experience in the pharmaceutical industry, including biopharmaceutical R&D, manufacturing and quality management. He has accumulated solid knowledge and deep industry experience by working in a number of reputable companies, including being a group leader at Genentech, Invitrogen Corporation and Cellular Dynamics International, a chief technical officer at A-Bio Pharma Pte. Ltd and a director of biotechnology at the Luye Group.

Mr. Wang Shenghan, chief financial officer, has over 20 years of experience in accounting and corporate finance. Mr. Chi Guangming, vice president of business operation center, has over 31 years of experience in the pharmaceutical industry. See "Directors, Supervisors and Senior Management" for further details of our management team.

Our management team comprises industry veterans who provide us with the whole-suite experience and capabilities for an integrated biopharmaceutical platform. For example, our management team has 52 industry experts with extensive experience across drug development, clinical development, CMC, quality control, regulatory affairs, marketing, and commercialization. More than 66% of our management team has a Master's or above degree.

Moreover, our seasoned management team and our achievements to which they have significantly contributed are also endorsed by 21 reputable Pre-[**REDACTED**] Investors which have made meaningful and valuable investments in us during the past two years, showing their trust and confidence in the leadership of our management team.

OUR STRATEGIES

Our vision is to become a leading biopharmaceutical company. We plan to expand our overseas footprint leveraging our aforementioned strengths and the leading position we are thriving to maintain in China. In order to achieve our vision and goals, we plan to pursue the following strategies.

Accelerate clinical development of our pipeline products towards commercialization in selected overseas markets

As of the Latest Practicable Date we had a total of 13 drug candidates, 11 of which had entered or completed clinical trials or received the IND approvals from the CDE, comprising one drug candidate with BLA approved, three in Phase 3 clinical trial, one in Phase 2 clinical trial, four in Phase 1 clinical trial, and two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU. We will continue to accelerate the clinical development of our pipeline products in China and overseas markets, such as the United States and the EU, for selected drug candidates to achieve speed-to-market. Beyond China, the United States and the EU, we also plan to strategically expand the clinical development of some of our pipeline products to selected regions in consideration of, among others, local market size, addressable patients, complexity of regulatory affairs, and competitive landscape of each overseas market.

We will continue to accelerate clinical trials of drug candidates and regulatory approval towards commercialization. Specifically, in order to launch potential first-to-market biosimilar drugs with leading market share, we will continue to strengthen our competitive edge on biosimilar drug development to enhance commercialization visibility. We will also implement our first-to-market clinical development strategy, especially for our innovative drug candidates focusing on oncology with unmet medical needs, to accelerate the clinical trial and regulatory approval. For example, for BA6101, we have obtained its regulatory approval to commence commercialization in November 2022 in China and are currently conducting its Phase 1 clinical trial in the EU. For BA1102, which is currently under Phase 3 clinical trial in China, we plan to submit its BLA in the first quarter of 2023 in China. For BA9101 and BA5101, which are currently under Phase 3 clinical trial in China, we plan to submit their BLAs in the first half of 2024 in China.

To strengthen our innovative drug pipeline and accelerate clinical development, with excellent drug development skills, we seek to maintain a risk-balanced portfolio with a strategic combination of mature targets and new targets aiming to become first-in-class drugs. For example, for BA1106, we plan to pursue global development with a variety of solid tumors. For LY-CovMab, which has completed Phase 1 clinical trial in China, we are conducting Phase 2 clinical trial in China.

Combination therapy with immuno-oncology therapy has witnessed increasing market acceptance for cancer treatment in recent years according to the Frost & Sullivan Report. Immuno-oncology therapy is designed to stimulate the patient's own immune system to generate or enhance an antitumor immune response in order to control or clear cancer cells. Due to its ability to provide durable remissions while being generally well-tolerated in certain patients with advanced cancers, the discovery and development of immuno-oncology therapy in recent years mark a milestone in cancer treatment. Leveraging our own robust product pipeline, we plan to selectively pursue combination therapy opportunities within our own portfolio such as BA1104 and BA1201 and accelerate relevant clinical trials and marketing approvals. We believe this strategy will help to lower drug development cost and further enriches our portfolio.

Enrich our innovative antibody portfolio to maximize our long-term commercial potential

Leveraging our strong R&D capability and proprietary technology platforms, we will continue to develop innovative drug candidates with strategically selected antibody targets and huge market potential. For example, we will continue to optimize our proprietary technology platforms to support the development of our innovative drug pipeline and advance clinical studies for new programs. We will also selectively pursue strategic collaborations with respect to product license-in to enrich our portfolio and support our long-term sustainable growth. In particular, we will prioritize license-in of products and product candidates focusing on oncology, with innovative targets or developed through advanced technology platforms to enrich our portfolio and strengthen R&D competitiveness. We plan to enhance our R&D resources by hiring talent with extensive international drug discovery and development experience and by improving our R&D facilities and infrastructure.

Further strengthen our marketing capability and accelerate the commercialization of our drug candidates leveraging our experience in commercializing Boyounuo® (BA1101)

We will continue to strengthen our commercialization capability, which is critical to our future success and profitability. Particularly, we plan to enhance the market share of Boyounuo® (BA1101) by expanding our sales and marketing team and strengthening our distribution channels to cover more target hospitals. Our distributors and promoters support us in the sales of and marketing of our products. Therefore, we plan to broaden our nationwide sales and distribution network through collaboration with sizable distributors having comprehensive distribution channels to reach more target hospitals with potential strong demand of our products. We will continue to expand our experienced and professional sales and marketing team in China, which mainly focuses on market access, medical affairs, and any other promotional initiatives in the therapeutic areas of oncology, metabolism, autoimmunity and ophthalmology. To promote our products nationwide, we will selectively enter into promotion agreements with reputable pharmaceutical companies and continue to collaborate with leading key opinion leaders in market education and product promotion. For hospital coverage, we will enhance the penetration rate of hospitals in China with tailored strategies for our specific products.

Establishing our marketing network and expanding our overseas footprint is instrumental to our vision of becoming a leading global biopharmaceutical company. We plan to expand our presence into international markets through a number of ways in selected markets or regions including accelerating clinical trial plans, identifying and working with suitable distributors and collaborating with international reputable industry players on business development.

Continue to expand in-house manufacturing capability

To support the growing sales of Boyounuo® (BA1101) and anticipated upcoming product launches, we plan to increase our investment in manufacturing equipment to expand manufacturing capacity, including two production lines each with three 2,000L single-use bioreactors for commercial production, to fulfill the anticipated large demand for commercialized products. We will develop and optimize in-house process technologies, upgrade our production facilities, enhance production know-how, as well as introduce a new technology platform, with a view to retaining high cost efficiency and production quality. We also plan to expand our in-house manufacturing and quality control team by attracting and retaining experienced talent with in-depth know-how.

Explore collaboration with reputable international partners to expand overseas presence

Our integrated biopharmaceutical platform built upon in-house capabilities throughout the entire biologics value chain enables us to expand our overseas presence. We will maximize the value of our platform by exploring collaboration with reputable international partners in a number of ways. For example, we plan to selectively enter into strategic cooperation including license-out or co-development with international partners to facilitate the clinical development and commercialization of our drug candidates overseas, broadening our geographic coverage. For example, we may cooperate with business partners including promoters and distributors to commercialize BA1102, BA6101, BA9101 and BA5101. We may explore co-development opportunities with leading global pharmaceutical companies and academic institutions to enhance our technology platforms. To commercialize our drug candidates outside of China to maximize their market potential, we will selectively collaborate with strategic partners. Finally, we plan to enter into license-in collaboration with selected international partners, including products at pre-clinical and clinical development stages, and products that have completed clinical trials, where we can leverage our regulatory affairs and commercialization capability to commercialize the in-licensed products and diversify our future revenue stream. We will select international partners which conduct R&D in the same indication areas with ours or have products or product candidates complementary to our product candidates, especially having late-stage clinical product candidates in oncology, diabetes, and orthopedics, with certain validation of clinical results.

OUR PORTFOLIO

Our portfolio comprised three Core Products, one commercialized product and ten other drug candidates as of the Latest Practicable Date. Our drug candidates in development include both innovative and biosimilar drugs. As of the Latest Practicable Date, we had launched a biosimilar product commercially, namely Boyounuo® (BA1101), and we were developing eight innovative antibody candidates and five biosimilar candidates in our pipeline, 11 of which had entered or completed clinical trials or received the IND approvals from the CDE, comprising (i) one drug candidate with BLA approved, (ii) three in Phase 3 clinical trial, (iii) one in Phase 2 clinical trial, (iv) four in Phase 1 clinical trial, and (v) two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU.

Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phases 1 and 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®.

The following table summarizes our Commercialized Product and drug candidate pipeline under development in China and worldwide across various therapeutic areas as of the Latest Practicable Date:

	Therapeutic area	Product (reference drug)	Target	Indication	Commercial rights	Clinical trial region	Pre-clinical	IND	Phase 1	Phase 2[10]	Phase 3	BLA filed	BLA approved
Innovative Antibody Portfolio	Infectious Disease	★ LY-CovMab[1]	SARS-CoV-2 spike protein	COVID-19	Worldwide	China							
		BA-CovMab	SARS-CoV-2 spike protein	COVID-19	Worldwide	China							
	Oncology	BA1105	Claudin 18.2 (ADCC)	Advanced gastric cancer, metastatic pancreatic cancer, and adenocarcinoma of the esophagogastric junction	Worldwide	China							
		BA1301	Claudin 18.2 ADC	Gastric cancer, pancreatic cancer, and esophageal cancer	Worldwide	China							
		BA1201	PD-L1/TGF-β	SCLC, NSCLC, cervical cancer, urothelial carcinoma, and advanced gastrointestinal tumors	Worldwide	China							
		BA1202	CEA/CD3	CRC, pancreatic duct adenocarcinoma, etc.	Worldwide	China							
		BA1106	CD25	Solid tumors	Worldwide	China							
	Autoimmunity	BA2101	IL4R	Atopic dermatitis, asthma, sinusitis, pruritus, urticaria, etc.	Worldwide	China							
Biosimilar Portfolio	Oncology	Boyounuo®* (BA1101, Avastin® biosimilar)[2]	VEGF	mCRC, advanced metastatic or recurrent NSCLC, recurrent glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer, and cervical cancer	Worldwide	China							
		★ BA1102 (Xgeva® biosimilar)[3]	RANKL	Bone metastases from solid tumors, and GCTB	Worldwide	China							
						Overseas							
		BA1104 (Opdivo® biosimilar)[4]	PD-1	Melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma	Worldwide	China							
						Overseas							
	Metabolism	★ BA6101 (Prolia® biosimilar)[5]	RANKL	Osteoporosis[6]	Worldwide	China							
						Overseas							
		BA5101 (Trulicity® biosimilar)[7]	GLP-1	Type 2 diabetes	Worldwide	China[11]							
						Overseas							
	Ophthalmology	BA9101 (Eylea® biosimilar)[8] [9]	VEGF	wAMD, RVO, DME, and DR	Worldwide[9]	China							
						Overseas							

Notes:

★ Denotes our Core Products.

* Denotes our Commercialized Product.

(1) We expect to submit the BLA of LY-CovMab in 2024. For more details, see "Business — Our innovative antibody portfolio — Our Core Product: LY-CovMab".

(2) The generic name of Boyounuo® (BA1101) is bevacizumab. We entered into an agreement with AstraZeneca China with respect to Boyounuo® (BA1101) on May 26, 2021, as amended by a supplemental agreement dated March 7, 2022, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. For more details, see "— Our biosimilar portfolio — Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®).

(3) The generic name of BA1102 is denosumab. We expect to submit the BLA of BA1102 in the first quarter of 2023 in China. The results of the Phase 1 clinical trial in the EU are expected to become available in the second half of 2023. Although BA1102 and BA6101 contain the same active agent, denosumab, they were developed as separate product candidates rather than expansion of indications of each other. The generic name of BA1102 is denosumab. For more details, see "— Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)".

(4) The generic name of BA1104 is nivolumab. For more details, see "Business — Our biosimilar portfolio — BA1104 (a biosimilar to Opdivo®)".

(5) The generic name of BA6101 is denosumab. We received the regulatory approval to commence commercialization in November 2022 in China. It is also currently under Phase 1 clinical trial in the EU, the results of which are expected to become available in the second half of 2023. For more details, see "— Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)".

(6) Treatments of various osteoporosis consist of (i) treatment of postmenopausal women with osteoporosis at high risk for fracture, (ii) treatment to increase bone mass in men with osteoporosis at high risk for fracture, (iii) treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, (iv) treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and (v) treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

(7) The generic name of BA5101 is dulaglutide. For more details, see "Business — Our biosimilar portfolio — BA5101 (a biosimilar to Trulicity®)".

(8) The generic name of BA9101 is aflibercept. We expect to submit the BLA of BA9101 in the first half of 2024 in China. For more details, see "— Our biosimilar portfolio — BA9101 aflibercept intraocular injection (a biosimilar to Eylea®)".

(9) We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, pursuant to which we are responsible for conducting certain initial stages of the Phase 3 clinical trial and commercial production as well as submitting the BLA of BA9101 and OcuMension is responsible for completing the rest of Phase 3 clinical trial and promoting and commercializing BA9101 in China. The term of the agreement ends on the tenth anniversary following the date of first delivery of BA9101 after marketing approval has been obtained. For more details, see "— Commercialization, sales, marketing and distribution — R&D partner and promoter".

(10) In the PRC, the NMPA has issued a number of guidelines encouraging biosimilar research and development, including the Biosimilar Guidelines, which set out the regulatory framework for registering and evaluating new biosimilar candidates. In general, the NMPA requires that biosimilars match the relevant reference drugs in terms of indications, usage guidelines and safety information. In addition, the biosimilar approval pathway is established based on the scientific objective of proving that there are no clinically-meaningful differences in the safety and efficacy of biosimilars when compared to the reference drug. Based on this principle, there is generally no need to conduct a Phase 2 clinical trial for biosimilars since the proper dose assuring safety and efficacy has already been determined for the reference product.

The following table sets forth the key tasks and outcome of our R&D conducted on each of the Core Products as of the Latest Practicable Date:

Core Products	Commencement date[1]	Completion date[2]	Task	Outcome
BA1102	April 2021	N/A	• Ongoing Phase 3 clinical in China	• The Phase 3 clinical trial for the treatment of bone metastases from solid tumors was ongoing, and thus safety and efficacy findings were not yet available.
	December 2019	July 2021	• Phase 1 clinical trial in China	• Based on the data collected and analyzed in the Phase 1 clinical trial, we concluded that a single dose of BA1102 or Xgeva® by subcutaneous injection in healthy subjects was bioequivalent, with similar PK and PD profiles. They show good overall safety and tolerability, and similar immunogenicity and safety profiles.
	December 2020	N/A	• Ongoing international Phase 1 clinical trial by virtue of BA6101's clinical trial in the EU	• The international Phase 1 clinical trial was ongoing, and thus PK/PD and safety findings were not yet available.
	July 2015	August 2016	• Pre-clinical research in China	• Because BA1102 and BA6101 contain the same active agent, denosumab, and have the same mechanism of action, we have performed pre-clinical studies of BA6101 including pharmacokinetic and toxicokinetic studies and molecular pharmacology, pharmacodynamics, immunogenicity and toxicity comparison studies in China.

Core Products	Commencement date[1]	Completion date[2]	Task	Outcome
BA6101	June 2019	August 2021	• Phase 3 clinical trial in China	• Based on the data collected and analyzed, we concluded that in the Phase 3 clinical trial of BA6101, subcutaneous injection of BA6101 every six months significantly increased the lumbar spine, hip, femoral neck, and trochanter bone mineral density ("**BMD**") and decreased bone turnover markers serum type 1 C-telopeptide ("**S-CTX**") and procollagen type 1 N-terminal peptide ("**P1NP**") in postmenopausal women with osteoporosis at high risk of fracture, compared with placebo. BA6101 was generally safe and well tolerated, and no unexpected adverse reactions occurred. Efficacy and safety profiles were similar compared to previous studies of the reference drug, Prolia®.
	December 2020	September 2021	• Phase 1b clinical trial in China	• Based on the data collected and analyzed in the Phase 1b clinical trial, we concluded that a single dose of BA6101 or Prolia® by subcutaneous injection in healthy adult male subjects was bioequivalent, with similar PK and PD profiles. They show good overall safety and tolerability, and similar immunogenicity and safety profiles.
	January 2018	May 2019	• Phase 1a clinical trial in China	• After a single-dose subcutaneous injection of BA6101 in healthy subjects, C_{max} was characterized by a linear PK within the dose range of 18 - 120 mg. The C_{max} and AUC were characterized by linear PK within the dose range of 60 – 120 mg. All subjects were negative for ADA. The single-dose subcutaneous injection of BA6101 (18mg, 60 mg and 120 mg) showed good overall safety and tolerability in healthy subjects.

Core Products	Commencement date[1]	Completion date[2]	Task	Outcome
	December 2020	N/A	• Ongoing international Phase 1 clinical trial in the EU	• The international Phase 1 clinical trial was ongoing, and thus PK/PD and safety findings were not yet available.
	July 2015	August 2016	• Pre-clinical pharmacokinetic and toxicokinetic studies and molecular pharmacology, pharmacodynamics, immunogenicity and toxicity comparison studies in China	• Compared with Prolia®, BA6101 has the same PK profile; the binding activity and inhibitory effect are similar; the toxic reactions are of the same nature and similar degree, without occurrence of any new toxic reactions, and the two drugs have similar toxicokinetic profiles. Therefore, BA6101 and Prolia® are biosimilars in terms of PD, PK, tissue cross-reactivity, and toxicokinetics.
LY-CovMab	August 2021	N/A	• Ongoing Phase 2 clinical trial in China	• The Phase 2 clinical trial for LY-CovMab remained ongoing, and thus its efficacy, safety, PK and immunogenicity findings were not yet available.
	November 2020	May 2021	• Phase 1 clinical trial in China	• The PK characteristics of LY-CovMab were positively correlated with dosage and LY-CovMab of different dosages showed favorable tolerability.
	July 2020	October 2020	• Pre-clinical toxicology studies in China	• Pre-clinical toxicology studies demonstrated that LY-CovMab was unlikely to cause ADE effects.
	June 2020	September 2020	• Pre-clinical PD/PK studies in China	• Results of pre-clinical PD studies showed that LY-CovMab had high affinity with RBD *in vitro*, effectively blocked the binding of ACE2 to RBD, had a clear virus neutralization effect and also had excellent virus neutralization activity *in vivo*. • The results of the safety pharmacology test in rhesus monkeys showed that LY-CovMab at doses of 50, 200 and 800 mg/kg had no significant effect on the central nervous system, cardiovascular system and respiratory system.

Notes:

(1) In terms of the clinical trial, the commencement date refers to the date of the first patient enrollment.

(2) In terms of the clinical trial, the completion date refers to the date of the clinical trial report.

OUR BIOSIMILAR PORTFOLIO

Overview

A biosimilar is a biological product which is highly similar to and has no clinically-meaningful differences from an existing approved reference product. Biosimilar manufacturers must develop the proposed biosimilar independently of the reference product, as they do not have access to the reference's molecular cloning (or a set of experimental methods in molecular biology that are used to assemble recombinant DNA molecules for the production of the biological molecule), primary cell bank, details of the production process nor the active drug substance(s). Generally, the development process requires that a biosimilar candidate undergoes clinical studies to demonstrate that it has no clinically-meaningful differences (in terms of both efficacy, safety and immunogenicity) from the reference product already approved by certain regulatory authorities, including the NMPA, FDA and EMA, notwithstanding minor differences in clinically-inactive components. The biosimilar candidate must undergo this regulatory review process, which for the NMPA, FDA and EMA is specially adapted for biosimilars, in order to receive approval for commercialization. See "Regulatory Overview" for further details on the NMPA, FDA and EMA approval processes.

Once approved and after expiry of the reference drug's major patents, the biosimilar can proceed to be commercialized. In order to be competitive against reference drugs, biosimilars are generally priced as affordable alternatives, enabling them to be potentially more widely-available, especially in markets where access to the reference drugs may be limited due to prohibitive pricing or other economic barriers. In the EU, which has had a biosimilar regulatory pathway since 2005, biosimilars have demonstrated potential to take market share from originator products and expand patient access.

In the PRC, which we expect to be a key market for all of our biosimilar candidates, the NMPA has issued a number of guidelines encouraging biosimilar research and development, including the Biosimilar Guidelines, which set out the regulatory framework for registering and evaluating new biosimilar candidates. In general, the NMPA requires that biosimilars match the relevant reference drugs in terms of indications, usage guidelines and safety information. In addition, the biosimilar approval pathway is established based on the scientific objective of proving that there are no clinically-meaningful differences in the safety and efficacy of biosimilars when compared to the reference drug. Based on this principle, there is generally no need to conduct a Phase 2 clinical trial for biosimilars since the proper dose assuring safety and efficacy has already been determined for the reference product. As advised by our PRC Legal Adviser, the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) and the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) do not require that Phase 3 clinical trials may be conducted only after Phase 1 or Phase 1b clinical trials are completed. We believe that this approach expedites the R&D process for us and will

facilitate faster approval and commercialization of our products. See "Risk Factors — Risks relating to the development, clinical trials and regulatory approval of our drug candidates — Clinical development involves a lengthy and expensive process with no assured outcome" for further details.

Our biosimilar portfolio includes one commercialized product, namely, Boyounuo® (BA1101) and other advanced biosimilar candidates including BA1102, BA6101, BA9101, BA1104 and BA5101, each as described in more detail below.

Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®)

Overview

We developed Boyounuo® (BA1101) as an Avastin® (bevacizumab) biosimilar, which is our first commercialized antibody drug product. Boyounuo® (BA1101) has been granted the use of the generic name Bevacizumab Injection in China by the NMPA. Bevacizumab is a monoclonal antibody drug approved by the NMPA mainly for the treatment of mCRC, advanced metastatic or recurrent NSCLC, recurrent glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer. Bevacizumab is included in the most recent NRDL for the indications including mCRC, advanced metastatic or recurrent NSCLC and recurrent glioblastoma, which became effective on January 1, 2022. Based on data collected and analyzed from our Phase 3 clinical trial completed in June 2020, we concluded that the trial achieved bioequivalence in both primary and secondary endpoints. We received regulatory approval for Boyounuo® (BA1101) from the NMPA for the indication of mCRC and advanced metastatic or recurrent NSCLC in April 2021 and we commenced commercial sales of Boyounuo® (BA1101) in May 2021. The shelf-life of Boyounuo® (BA1101) is 24 months. Boyounuo® (BA1101) was registered as therapeutic biological product (治療用生物製品) according to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) and the Registration Classification of Biological Products and Requirements for Application Materials (《生物製品註冊分類及申報資料要求》).

Subsequent to the successful launch of Boyounuo® (BA1101) in May 2021, we further made several achievements including (i) obtaining the NMPA approvals to extrapolate its indications to recurrent glioblastoma in July 2021 and epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in February 2022, which further broaden the product's market potential, and (ii) publishing two papers in *Cancer Communications* and *Expert Opinion on Biological Therapy* in May and December 2021, respectively, covering the clinical trial comparing its efficacy and safety with that of Avastin® in first-line treatment of Chinese patients with advanced metastatic or recurrent NSCLC, as well as the study comparing its PK profiles, safety and immunogenicity with those of Avastin® in healthy Chinese males.

We have entered into an agreement with AstraZeneca China with respect to Boyounuo® (BA1101) on May 26, 2021, as amended by a supplemental agreement dated March 7, 2022, under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. For more details, see "— Our biosimilar portfolio — Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®) — Collaboration arrangements and commercialization plans".

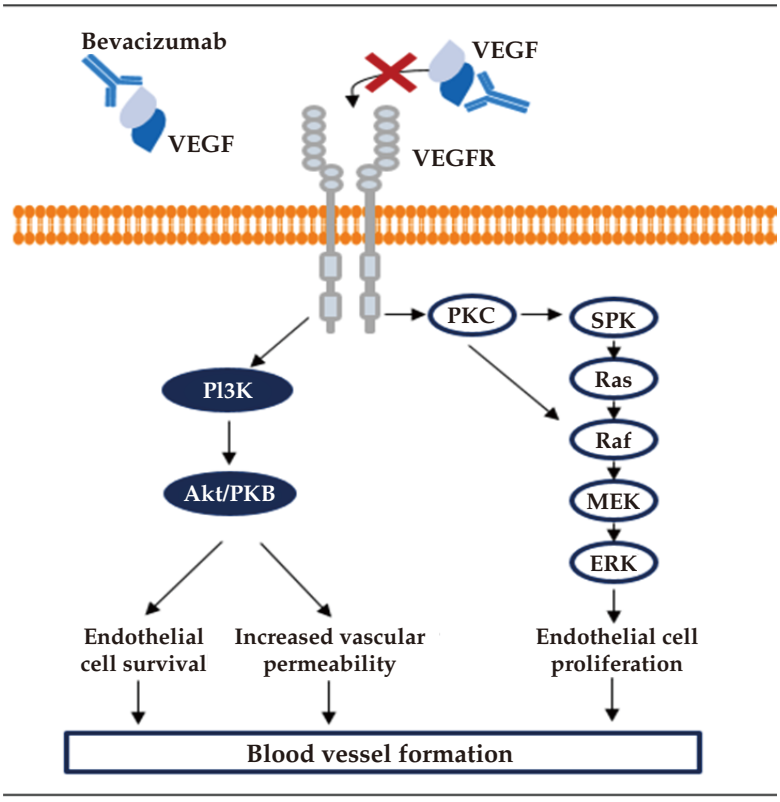
Background of reference drug

Bevacizumab was developed by Roche. It initially received the FDA approval under the brand name of Avastin® for the treatment of mCRC in 2004 and advanced metastatic or recurrent NSCLC in 2006. Avastin® was launched in China in 2010. Bevacizumab was first added to the NRDL (2017 edition). Bevacizumab is typically administered through intravenous infusion. Major patents for bevacizumab have expired including those in the United States in 2019, the EU in 2020 and China in 2018. Avastin® is distributed globally by Roche, and is listed on the WHO List of Essential Medicines. In 2021, the global sales of Avastin® amounted to US$3.3 billion, while the sales in China amounted to RMB3.3 billion according to the Frost & Sullivan Report.

Depending on the jurisdiction, approved indications of Avastin® may include mCRC, advanced metastatic or recurrent NSCLC, recurrent glioblastoma, metastatic renal cell carcinoma, hepatocellular carcinoma, metastatic breast cancer, persistent, recurrent or metastatic cervical cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, etc. In China, Avastin® has been approved for indications, including mCRC, advanced metastatic or recurrent NSCLC, recurrent, glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer, cervical cancer, etc.

Mechanism of action

Bevacizumab binds to VEGF and prevent the interaction with VEGF to its receptors, VEGFRs, on the surface of endothelial cells and thereby inhibiting VEGF's angiogenic activity. By exerting both anti-vascular and anti-angiogenesis effect on vessel surrounding the tumor, bevacizumab can result in both reduction of tumor size and inhibition of tumor growth.



Source: Frost & Sullivan report

Current therapies

The dosage and administration of bevacizumab vary by indications such as the following examples. All the treatment is indicated in the approval label by each competent authority such as the FDA and also mentioned in the NCCN guidelines.

mCRC: As a first-line and second-line therapy for advanced mCRC, the recommended dose when bevacizumab is administered intravenously in combination with fluoropyrimidine-based chemotherapy is 5 mg/kg every two weeks, 7.5 mg/kg every three weeks, respectively.

Advanced metastatic or recurrent NSCLC: As a first-line therapy for unresectable, advanced, recurrent or metastatic NSCLC, bevacizumab is administered at 15 mg/kg intravenously every three weeks in combination with platinum-based chemotherapy, followed by bevacizumab as a single agent.

Recurrent glioblastoma: As a first-line therapy for recurrent glioblastoma, bevacizumab is administered at 10 mg/kg intravenously every two weeks.

Epithelial ovarian, fallopian tube or primary peritoneal cancer: As a first-line therapy for epithelial ovarian, fallopian tube or primary peritoneal cancer, bevacizumab is administered at 15 mg/kg intravenously every three weeks in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent.

Cervical cancer: As a first-line therapy for cervical cancer, bevacizumab is administered at 15 mg/kg intravenously every three weeks in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.

Because bevacizumab inhibits blood vessel growth, which is a necessary part of the body's ability to heal wounds and develop collateral circulation solutions, its use may interfere with these normal functions and worsen existing conditions such as for patients with serious haemorrhaging or a recent history of haemoptysis. As a result, across studies, the most common adverse reactions observed in Avastin® patients (incidence rate over 10%) were: epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal haemorrhage, lacrimation disorder, pain and exfoliative dermatitis. Based on the drug's mechanism of action and safety information, the suitability of the drug should be evaluated before using bevacizumab, taking into consideration congenital hemorrhagic constitution or acquired coagulopathy, severe cardiovascular disease (such as coronary heart disease, congestive heart failure, hypertension, etc.), thromboembolism risk, recent hemoptysis, major surgery, etc.

Market opportunities and competition

According to the Frost & Sullivan Report, lung cancer ranked first by incidence and was the leading cause of cancer death in China in 2021, and NSCLC accounted for 85% of all lung cancer incidence. The number of new cases of lung cancer patients has increased from 840.2 thousand in 2017 to 953.8 thousand in 2021, with a CAGR of 3.2%. Influenced by the risk factors such as increased tobacco smoking and air pollution, new cases of lung cancer in China are expected to continuously increase to 1,243.9 thousand in 2030, with a CAGR of 3.0% from 2021 to 2030. For NSCLC patients at the late stage, anti-angiogenesis drugs including bevacizumab and recombinant human endostatin, as well as the immune check point inhibitors (i.e. PD-1 inhibitors) are recommended as first-line therapy, with bevacizumab and pembrolizumab having higher level of recommendation when compared with others.

CRC ranked third by incidence in China in 2021, reaching the incidence of 467.6 thousand in 2021 from 413.6 thousand in 2017, with a CAGR of 3.1%. Due to the adoption of early screening, the CRC incidence is projected to be 606.3 thousand by 2030, representing a CAGR of 2.9% from 2021 to 2030. In China, the CSCO guideline on colorectal cancer recommends using CPT analogue drug (irinotecan) in both conversion therapy of CRC and mCRC. Bevacizumab is the recommended option in combination therapy for first-line and second-line treatment.

In 2017, the incidence of ovarian cancer in China reached 52.0 thousand, which further reached 56.2 thousand in 2021, with a CAGR of 1.9%. It is predicted that the number will continue to grow, and reach 62.7 thousand in 2030, with CAGR of 1.2% from 2021 to 2030. Ovarian cancer usually refers to cancers that begin in the cells in the ovary, fallopian tube, or peritoneum. Among ovarian cancer, epithelial ovarian cancer is the most common type. As one of the antiangiogenic drugs, bevacizumab is valuable in the first-line treatment of ovarian cancer and in the treatment of platinum-sensitive relapse and platinum-resistant relapse ovarian cancer. Whether in first-line treatment or relapse treatment, chemotherapy combination with bevacizumab helps to prolong the patient's progression-free survival (the "**PFS**").

In 2017, the incidence of cervical cancer in China reached 114.2 thousand, which further increased to 119.4 thousand in 2021, with a CAGR of 1.1%. It is predicted that the number will continue to grow, and will reach 125.9 thousand in 2030, with CAGR of 0.6% from 2021 to 2030. The treatment of cervical cancer mainly includes surgery and radiotherapy. Chemotherapy is widely used in combination with surgery and radiotherapy and in the treatment of advanced recurrent cervical cancer. The early stage of cervical cancer is mainly treated by surgery, and the middle and late stage of cervical cancer is mainly treated by radiotherapy, supplemented by chemotherapy. Chemotherapy is widely used in the treatment of cervical cancer, using platinum (mainly cisplatin) based monotherapy or combination chemotherapy. According to the most recent NCCN and 2022 CSCO guidelines, bevacizumab is recommended as first-line therapy in combination with pembrolizumab and/or chemotherapy and recommended as second-line or subsequent therapy as monotherapy for recurrent/metastatic cervical cancer.

In 2017, the incidence of recurrent glioblastoma in China reached 51.5 thousand, which further increased to 56.4 thousand in 2021, with a CAGR of 2.3%. It is predicted that the number will continue to grow, and will reach 65.7 thousand in 2030, with CAGR of 1.7% from 2021 to 2030. Glioblastoma is the most common form of primary brain cancer and glioblastoma recurrence has become a clinically significant issue as most patients experience recurrence in situ. In China, current treatment options of recurrent glioblastoma include reoperation, concurrent radiotherapy and chemotherapy with temozolomide, tumor treating fields and bevacizumab.

According to the Frost & Sullivan Report, the bevacizumab market size in China increased from RMB1.7 billion in 2017 to RMB9.0 billion in 2021, and is expected to increase to RMB18.4 billion in 2030, with a CAGR of 8.3% from 2021 to 2030. Bevacizumab was first included in the NRDL (2017 edition), resulting in greater market awareness and penetration, and we believe it will benefit our efforts to market Boyounuo® (BA1101). While Avastin® may become increasingly accessible, we expect that there will continue to be a significant gap between supply and demand. As more medical practitioners and patients become familiar with bevacizumab, we believe they will also become increasingly familiar with Boyounuo® (BA1101) as a more affordable bevacizumab to bridge the supply-demand gap which is expected to lead to significant market opportunities for affordable Avastin® (bevacizumab) biosimilars.

The following table illustrates the competitive landscape of marketed bevacizumab in China as of the Latest Practicable Date:

Brand name	Generic name	Company	Initial NMPA approval	Indications	Annual cost per patient[1] (RMB)	2021 China sales revenue (million RMB)	NRDL
Avastin®	Bevacizumab	Roche	2010-02-26	mCRC Advanced metastatic or recurrent NSCLC Cervical cancer Recurrent glioblastoma Hepatocellular carcinoma Epithelial ovarian, fallopian tube, or primary peritoneal cancer	~180,000	3,299	According to the NRDL (2021 edition) (in effect on January 1, 2022), only bevacizumab (Avastin®) indicated for the treatment of mCRC, metastatic/recurrent NSCLC, recurrent glioblastoma and unresectable HCC are included in Category B.[3]
Ankeda®	Bevacizumab-QL1101	Qilu Pharma	2019-12-06	mCRC Advanced metastatic or recurrent NSCLC	~139,440	3,500	
BYVASDA®	Bevacizumab-IBI305	Innovent	2020-06-17	mCRC Advanced metastatic or recurrent NSCLC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer Hepatocellular carcinoma	~138,480	NA	
Boyounuo®	**Bevacizumab-BA1101**	**Our Group**	**2021-04-30**	**mCRC** **Advanced metastatic or recurrent NSCLC** **Recurrent glioblastoma** **Cervical cancer** **Epithelial ovarian, fallopian tube, or primary peritoneal cancer**	**~137,640**	**158.7**	
Airuituo (艾瑞妥)	Bevacizumab-BP102	Suzhou Suncadia	2021-06-22	mCRC Advanced metastatic or recurrent NSCLC Recurrent glioblastoma	~138,480	NA	
Pubeixi (普貝希)	Bevacizumab-BAT1706	Bio-Thera Solutions	2021-11-17	Advanced metastatic or recurrent NSCLC mCRC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer	~137,640	NA	
Beianting (貝安汀)	Bevacizumab-MIL60	Betta Pharma	2021-11-24	Advanced metastatic or recurrent NSCLC mCRC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer	NA	NA	
Hanbeitai	Bevacizumab-HLX04	Henlius Biotech	2021-11-30	Advanced metastatic or recurrent NSCLC mCRC	NA	NA	
Pusintin®	Bevacizumab-TAB008	Tot Biopharm	2021-11-30	Advanced metastatic or recurrent NSCLC mCRC Recurrent glioblastoma Cervical cancer Epithelial ovarian, fallopian tube, or primary peritoneal cancer Hepatocellular carcinoma	~137,040	NA	

Notes:

(1) Annual cost per patient varies by treatment regimen and the cost listed is before medical insurance reimbursement.

(2) Bevacizumab is recommended in combination with chemotherapy for up to six cycles followed by administration as a single agent for a total of up to 22 cycles or until disease progression; however, treatment cycle varies by patient condition and is subject to physician discretion.

(3) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

(4) NA means not applicable or public information is not available.

Source: Frost & Sullivan Report

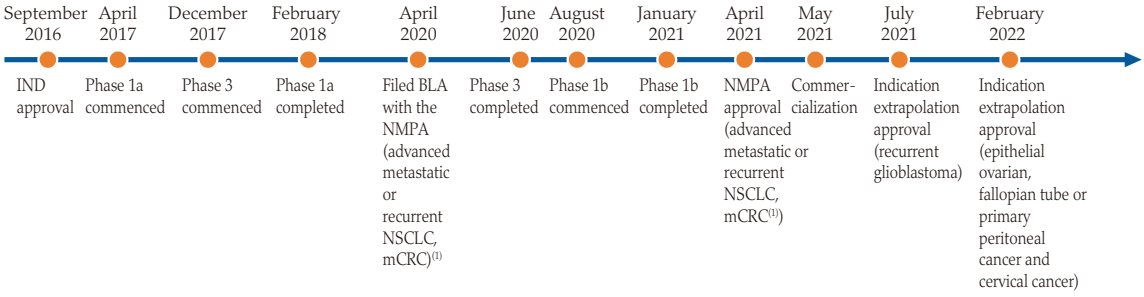
Boyounuo® (BA1101) is the third biosimilar to Avastin® launched in China. Subsequent to the launch of Boyounuo® (BA1101) in May 2021, we further obtained the NMPA approvals to extrapolate its indications to recurrent glioblastoma in July 2021 and epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in February 2022, which further broaden the product's market potential. Although the pricing of Boyounuo® (BA1101) is similar to those of competitors, we believe Boyounuo® (BA1101) is well positioned to compete in the market for bevacizumab and gain a leading market share in China, considering the significant market size of bevacizumab, our early-mover advantage in China and a broad indication coverage. In addition, we have a dedicated in-house sales and marketing team with extensive industry experience to develop and implement marketing and sales plans of Boyounuo® (BA1101). We also engaged experienced third-party promoters to publicize and maximize market potential of our products, including AstraZeneca China. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China.

Summary of clinical development history and results

We completed Phase 1 clinical trials and Phase 3 clinical trial for BA1101 for NSCLC. Based on the data collected and analyzed, we concluded that the Phase 1 and Phase 3 clinical trials of BA1101 achieved bioequivalence between BA1101 and Avastin® in both primary and secondary endpoints. The clinical trial results also demonstrated similarity to Avastin® in terms of immunogenicity and safety.

Clinical development

The chart below summarizes the development timeline of BA1101:



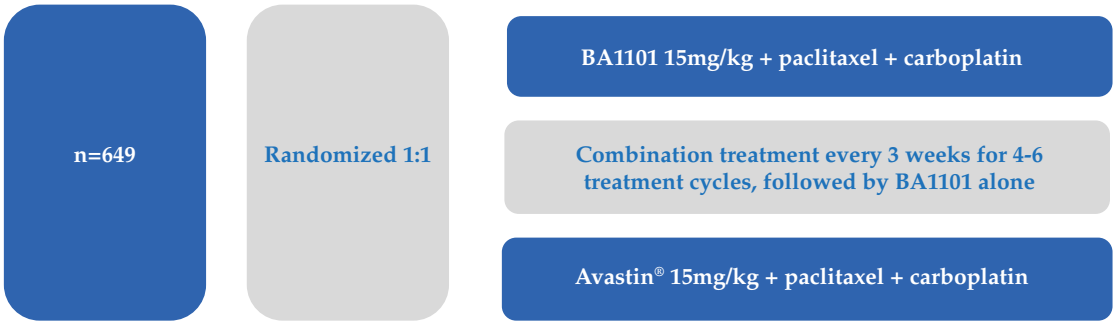
Note:

(1) According to the Technical Guidelines for Research, Development and Evaluation of Biosimilars (《生物類似藥研發與評價技術指導原則》), if the clinical similarity is confirmed in the comparative study, it may be considered to expand to other indications of the reference drug. As mCRC is one of the indications of Avastin®, we also applied BLA for the indication of mCRC together with the indication of advanced metastatic or recurrent NSCLC.

Phase 3 clinical trial

Study design. The Phase 3 clinical trial was a multi-center, randomized, double-blind study comparing the efficacy and safety of BA1101 with reference bevacizumab (Avastin®) combined with paclitaxel/carboplatin for stage IIIB-IV NSCLC patients with evaluable lesions, good physical status, and adequate organ functions.

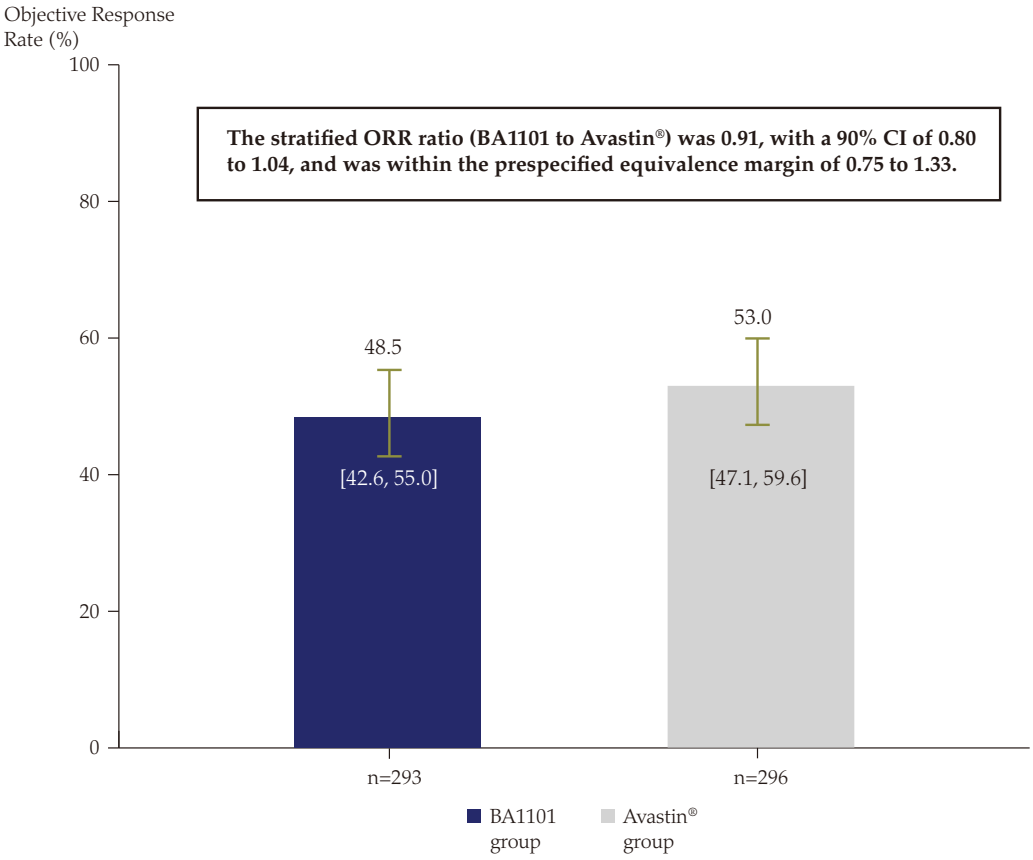
Patients from 67 centers across China were randomized in a ratio of 1:1 to receive BA1101 or Avastin® 15 mg/kg intravenously in combination with paclitaxel/carboplatin (combined treatment) every three weeks for four to six treatment cycles, followed by maintenance monotherapy with BA1101 until disease progression, intolerable toxicity, or death. The Phase 3 clinical trial, which was completed in June 2020, enrolled 649 subjects (divided into two study groups of 324 subjects for BA1101 group and 325 for Avastin® group).



The primary endpoint was objective response rate ("**ORR**") in accordance with Response Evaluation Criteria in Solid Tumors version 1.1 confirmed by independent radiological review committees ("**IRRC**").

Secondary endpoints included (i) disease control rate ("**DCR**"), (ii) duration of response ("**DoR**"), (iii) PFS, (iv) overall survival ("**OS**"), and (v) safety and immunogenicity across different treatment groups.

Efficacy. With respect to primary endpoint findings, as of the primary endpoint cut-off date on September 25, 2019, a total of 142 (48.5%) and 157 (53.0%) in the BA1101 and Avastin® groups achieved an objective response (all partial response), respectively. As shown in the diagram below, the stratified ORR ratio (BA1101 to Avastin®) was 0.91, with a 90% CI of 0.80 to 1.04, and was within the prespecified equivalence margin of 0.75 to 1.33. Consistent results were observed in ORR sensitivity analyses, including PPS or ITT-based stratified and unstratified ORR by IRRC and by investigators in full analysis set("**FAS**"), per-protocol sets ("**PPS**"), and intent-to-treat ("**ITT**") population. These results demonstrated the similarity of efficacy between the BA1101 group and the Avastin® group. DCRs from primary analyses were also similar in the two treatment groups. The following diagram sets forth the ORR findings in more detail:

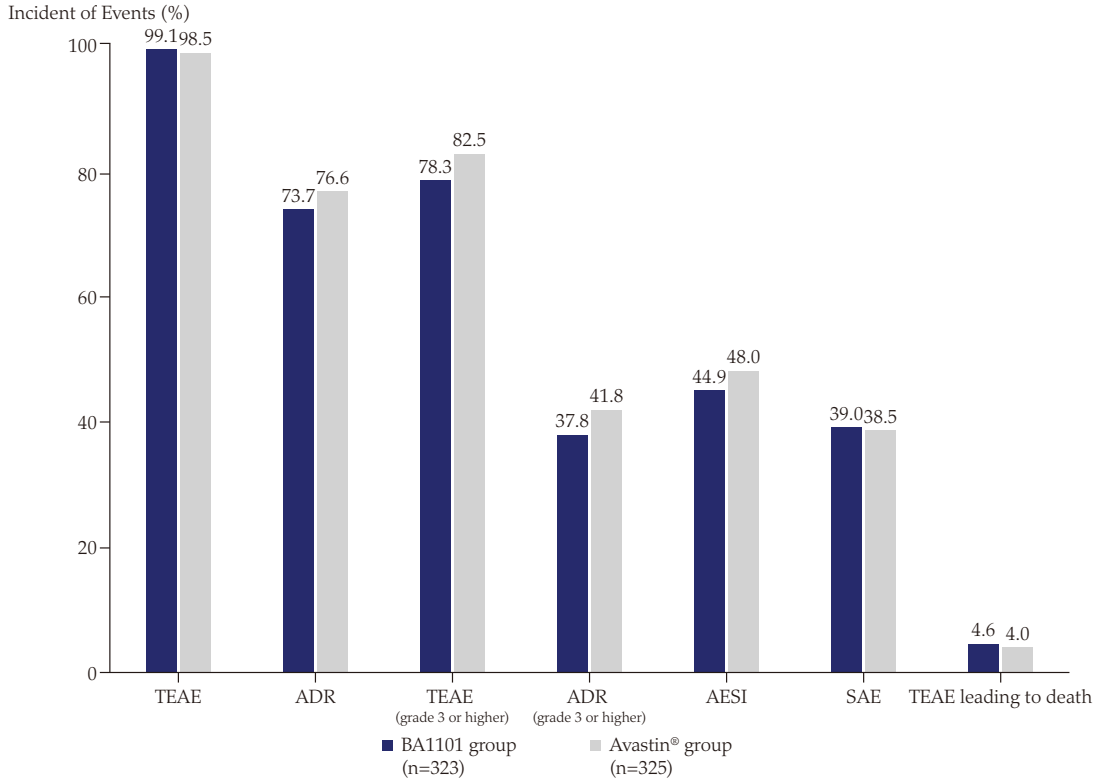


As of May 15, 2020, renewed efficacy results were reviewed by the investigators, and observed that the ORR was 56.0% in the BA1101 group and 58.8% in the Avastin® group in the FAS.

Secondary endpoint findings were as follows:

Parameters	BA1101 group	Avastin® group	ORR risk ratio (90% CI)
ORR	56.0%	58.8%	0.95 (0.85, 1.07)
DCR	95.6%	93.6%	1.03 (0.99, 1.06)
DoR (Month)	5.62 (4.96, 6.87)	5.72 (4.86, 7.06)	
PFS (Month)	7.16 (6.87, 8.28)	7.10 (6.74, 8.21)	
OS (Month)	24.38 (23.85, –)	22.97 (20.37, –)	
1-year OS rate (95% CI)	79.4 (74.6-84.5)%	78.1 (73.2-83.4)%	

Safety. Safety analysis was conducted on the first analysis cutoff date of September 25, 2019. There was no statistically significant difference in the incidence rates of treatment-emergent adverse events ("**TEAEs**"), study drug-related TEAEs ("**ADRs**"), serious adverse events ("**SAEs**") and incidence of adverse events of special interest ("**AESI**") between the BA1101 group and Avastin® group. The incidence rate of TEAEs was 99.1% and 98.5% in the BA1101 and Avastin® groups, respectively. The incidence rate of ADRs was 73.7% and 76.6% in the BA1101 and Avastin® groups, respectively. The incidence rate of SAEs was 39.0% and 38.5% in the BA1101 and Avastin® groups, respectively. The incidence rate of AESI was 44.9% and 48.0% in the BA1101 and Avastin® groups, respectively. The ADR with the incidence rate of 10.0% or higher includes leukopenia, neutropenia, anemia, thrombocytopenia, proteinuria, bone marrow failure, alopecia and nausea. Most study drug-related SAEs were rare with an incidence rate less than 1.0%, with only the incidence rate of bone marrow failure and thrombocytopenia over 1.0%. The following diagram sets forth the safety findings in more detail:



TEAE: treatment-emergent adverse events
ADR: study drug-related TEAE
AESI: AEs of special interest
SAE: serious adverse events

Immunogenicity. Anti-drug antibody ("**ADA**") and neutralizing antibody ("**NAb**") were detected for the study drugs. Of the 648 patients in the safety set, 13 (2.0%) were positive for ADA before the first cycle of treatment (7 [2.2%] in the BA1101 group vs. 6 [1.8%] in the Avastin® group). Six (0.9%) patients (three in each group) showed at least once ADA-positivity during the study of combined treatment, which were all transient. One patient showed transient post-treatment ADA-positivity. By September 25, 2019, all ADA-positive cases had changed to negative. No NAb-positive cases were found. There were no clinically-meaningful differences in immunogenicity across treatment groups. Given the low rate of ADA-positive data, no obvious effect of immunogenicity on pharmacokinetic and safety was observed.

Phase 1b clinical trial

Study design. The Phase 1b clinical trial was a single-center, randomized, double-blind, parallel-group study conducted in the Second Hospital of Anhui Medical University evaluating the PK, safety, tolerability, and immunogenicity of BA1101 compared to Avastin® in healthy male subjects. The Phase 1b clinical trial, which was completed in January 2021, enrolled 112 subjects (56 subjects in each study group) who received a single dose of either BA1101 or Avastin® (both 3 mg/kg).

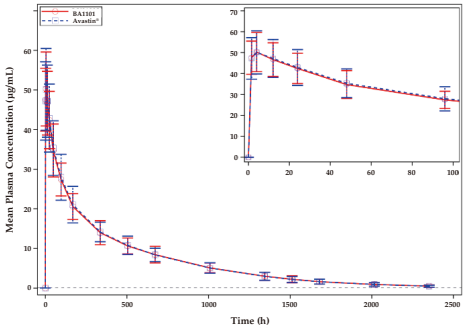
The primary endpoint was concentration-time curve ("**AUC**") from last quantifiable concentration ("$\mathbf{AUC_{0-t}}$").

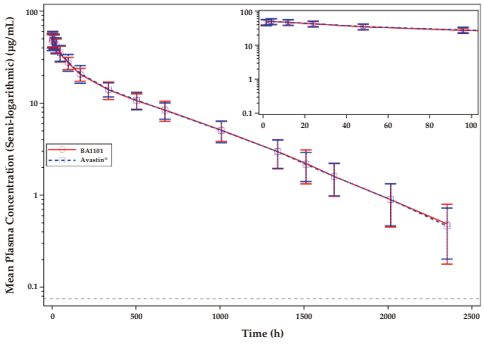
The secondary endpoints included observing: (i) the AUC from time zero to infinity ("$\mathbf{AUC_{0-\infty}}$"); (ii) maximum plasma concentration ("$\mathbf{C_{max}}$"); (iii) time to reach C_{max} ("$\mathbf{T_{max}}$"); (iv) systemic clearance ("**CL**"); (v) terminal half-life ("$\mathbf{t_{1/2}}$"); and (vi) volume of distribution ("$\mathbf{V_d}$"), etc.

The safety parameters of the study included adverse events that occurred during the clinical study, and clinical symptoms, abnormal vital signs and physical examinations, as well as abnormal clinical laboratory test values.

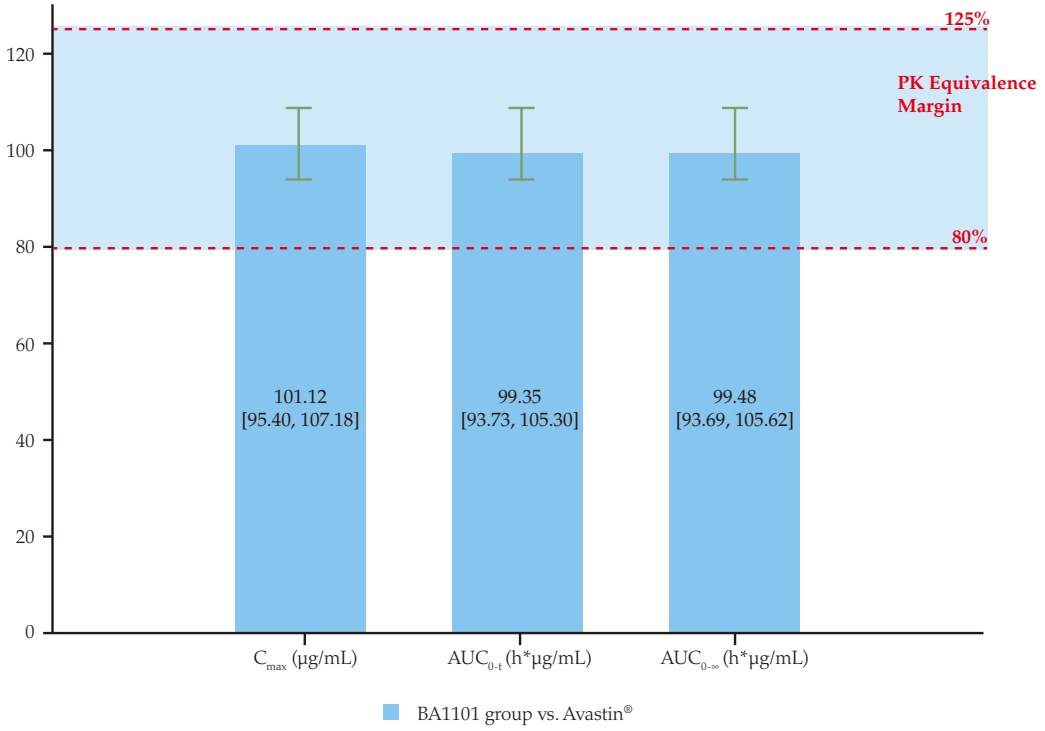
Immunogenicity was also evaluated based on the incidence rate of ADA-positive results and NAb-positive results.

PK. The mean plasma concentration-time profiles of the two study drugs were similar over the entire course of sampling. The 90% CIs of GMRs for BA1101/Avastin® of C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$ were all within a predefined bioequivalence margin of 80.00–125.00%. The following diagrams set out the findings in more detail:



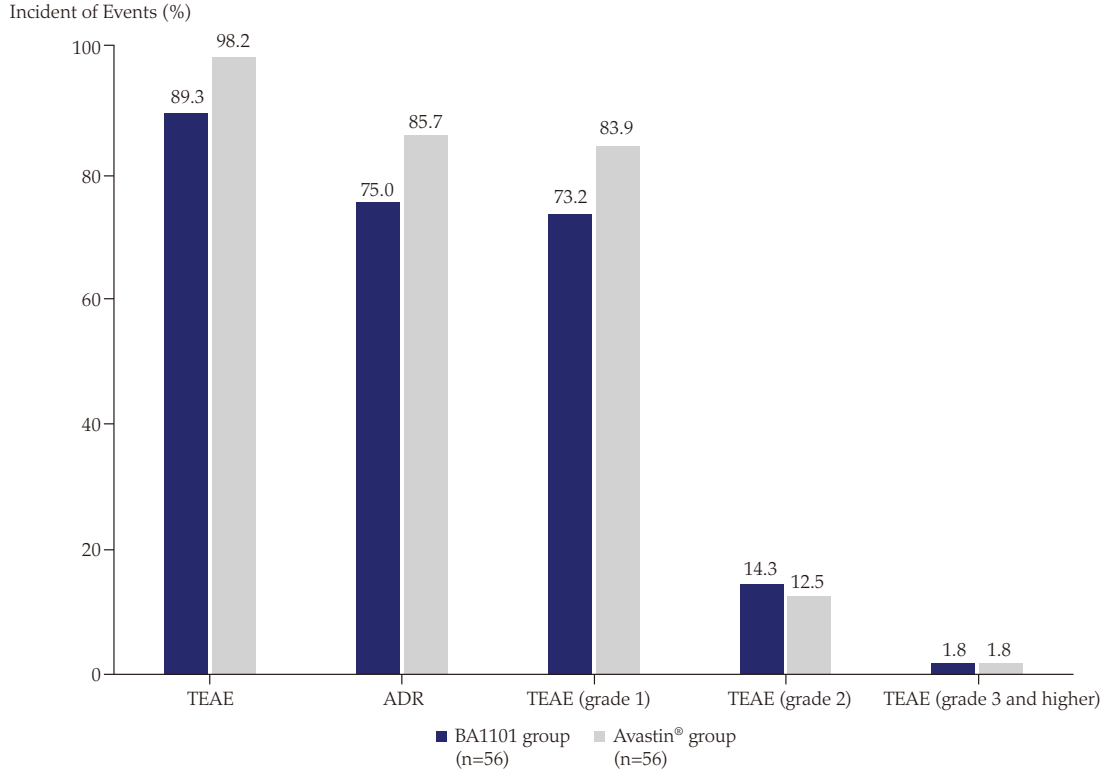


C_{max} AUC_{0-t} $AUC_{0-\infty}$ Least Square Geometric Mean Ratio



Safety. There was no statistically significant difference in the incidence and severity of adverse events between BA1101 and Avastin®.

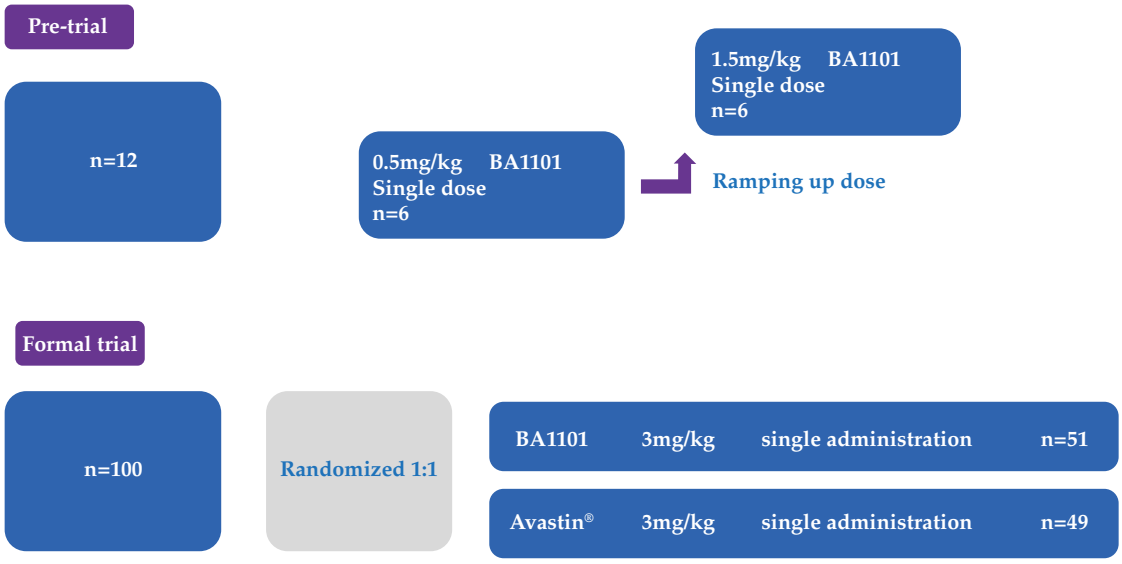
89.3% of BA1101 subjects experienced 211 AEs which were all TEAEs, and 75.0% of BA1101 subjects experienced 99 TEAEs related (all possibly related) to the study drug. Similarly, in the Avastin® group, 98.2% of the subjects experienced 217 AEs, and they were all TEAEs. Among them, 85.7% of the subjects experienced 115 TEAEs related (all possibly related) to the study drug. The incidence rate of ADRs was 75.0% and 85.7% in the BA1101 and Avastin® groups, respectively. The most common TEAEs with incidence for BA1101 and Avastin® were blood triglyceride increased, proteinuria and sinus bradycardia, and the most common TEAEs related (all possibly related) to the study drug with incidence for BA1101 and Avastin® were proteinuria, urinary tract infection and increase in alanine aminotransferase. The incidences of the most common TEAEs were comparable between the two groups. Over the study course, no SAEs, TEAEs leading to death or study discontinuation occurred in the two groups. Most TEAEs were grade 1 or grade 2 in severity; the majority resolved without intervention. One subject in each group experienced grade 3 TEAEs: blood triglyceride increased (possibly unrelated to study drug) two times in the BA1101 group, and alanine aminotransferase increased (possibly related to study drug) once in Avastin® group, respectively; all were resolved without intervention. The incidences of TEAEs at different severities were similar between the two groups. The following diagram sets forth the safety findings in more detail:



Immunogenicity. Immunogenicity findings also showed no statistically significant difference. None of the subjects in the BA1101 group had ADA-positive or NAb-positive results; a total of three subjects in the Avastin® group had ADA-positive results, all of which occurred near the end of the elimination phase with relatively low anti-drug antibody titers, and none of the subjects had NAb-positive results.

Phase 1a clinical trial

Study design. The Phase 1a clinical trial was a single-center, randomized, double-blind, parallel-group study evaluating the PK, safety, tolerability, and immunogenicity of BA1101 compared to Avastin® in healthy male subjects. The Phase 1a clinical trial, which was completed in February 2018, was divided into two parts, i.e., the pre-trial and the formal trial. The pre-trial was made up of 0.5 mg/kg and 1.5 mg/kg dose groups, with six persons in each group. The trial started with the 0.5 mg/kg dose group. After the 0.5 mg/kg dose was determined to be safe and tolerable, the trial for the 1.5 mg/kg dose group was carried out. The PK for 29 days were analyzed in the pre-trial. Among 100 subjects who were enrolled in the formal trial, we had 51 persons in the BA1101 group and 49 persons in the Avastin® group. Each trial group received a single intravenous infusion of BA1101 or Avastin® 3 mg/kg. Blood samples and relevant data were collected in both the pre-trial and the formal trial.



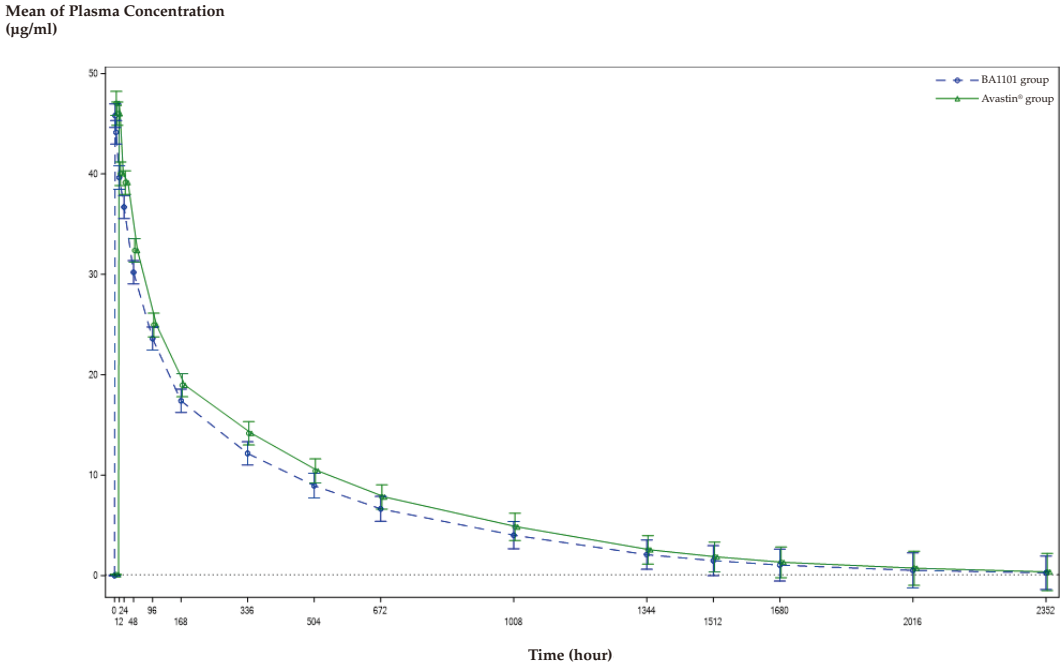
The primary endpoint was AUC_{0-t}.

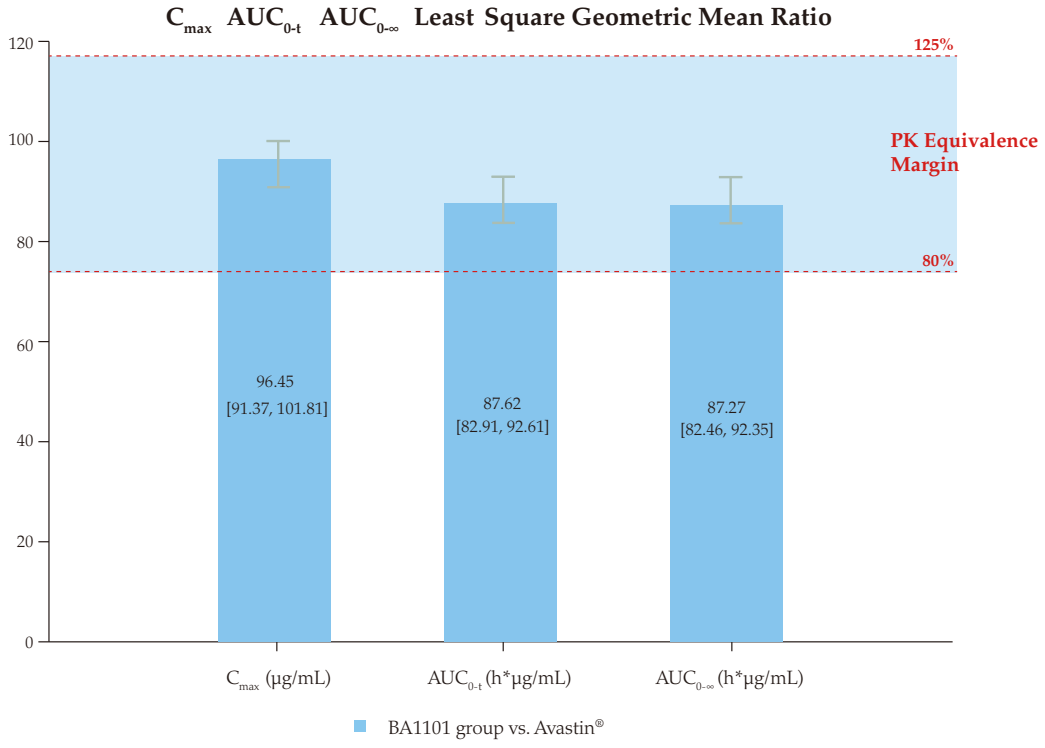
The secondary endpoints included observing: (i) $AUC_{0-\infty}$; (ii) C_{max}; (iii) CL; (iv) $t_{1/2}$; (v) V_d, etc.

The safety parameters of the study included adverse events that occurred during the clinical study, and clinical symptoms, abnormal vital signs and physical examinations, as well as abnormal clinical laboratory test values.

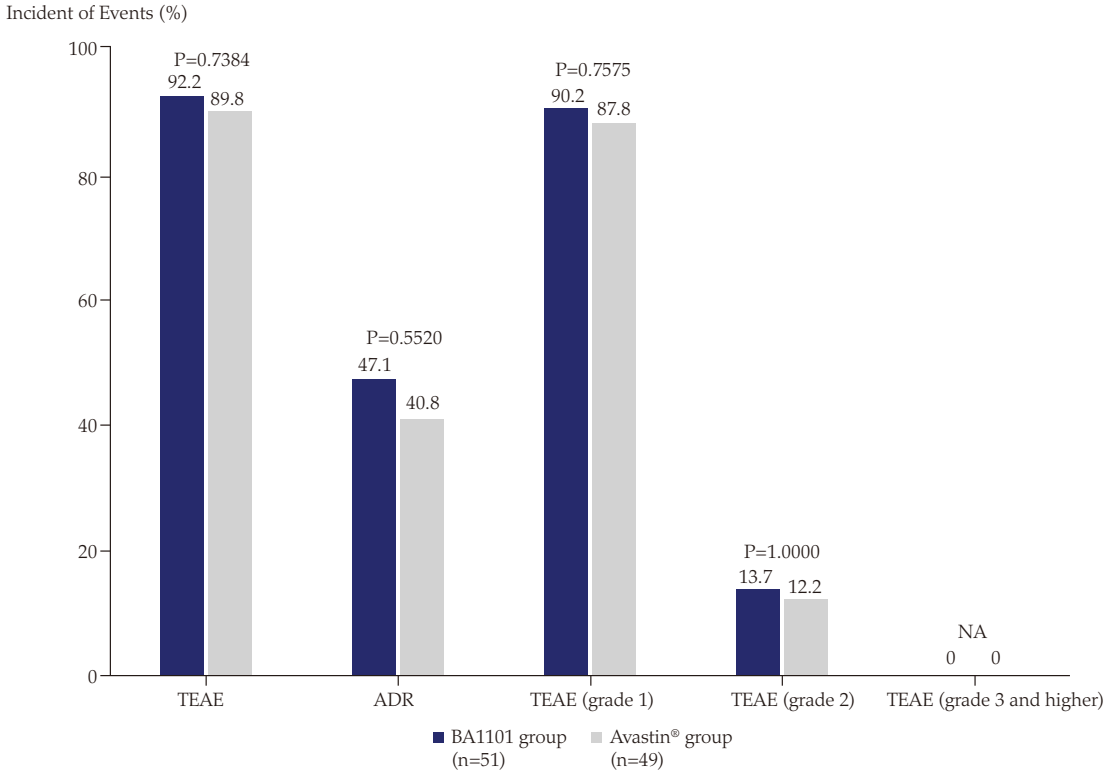
Immunogenicity was also evaluated based on the incidence rate of ADA-positive results and NAb-positive results.

PK. The mean plasma concentration-time profiles of the two study drugs were similar over the entire course of sampling. The 90% CIs of GMRs for BA1101/Avastin® of C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$ were all within a predefined bioequivalence margin of 80.00–125.00%. The following diagrams set out the findings in more detail:





Safety. There was no statistically significant difference in the incidence and severity of adverse events between BA1101 and Avastin®. The incidence rate of TEAE was 92.2% and 89.8% in the BA1101 and Avastin® groups, respectively. The incidence rate of ADRs was 47.1% and 40.8% in the BA1101 and Avastin® groups, respectively. The severity of TEAE was grade 1 and grade 2 for either group. None of grade 3 or higher TEAE, SAE and TEAE leading to death occurred to the BA1101 group or the Avastin® group. The following diagram sets forth the safety findings in more detail:



Immunogenicity. Immunogenicity findings also showed no statistically significant difference. Five subjects in each of the BA1101 group and the Avastin® group had the ADA-positive results during the study period.

Material communications and next steps

We received the approval from the NMPA to commence marketing and commercialization of BA1101 in April 2021. Ahead of receiving such approval, we:

(i) obtained a manufacturing permit for BA1101 from the NMPA Shandong Province Bureau in September 2019, which allows us to commence commercial production of Boyounuo® (BA1101) at our Yantai Site upon receiving regulatory approval from the NMPA and GMP certificate; and

(ii) obtained from the NMPA approval to extrapolate BA1101's indications to mCRC and advanced metastatic or recurrent NSCLC in April 2021.

We obtained from the NMPA the approvals to extrapolate BA1101's indications to recurrent glioblastoma in July 2021 and epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in February 2022.

Other than the above, we are not aware of any material concern from the NMPA or the CDE in connection with BA1101. As of the Latest Practicable Date, no material adverse change had occurred with respect to our NMPA approval for BA1101.

See "— Intellectual property" in this section for more details of intellectual properties which we have registered, maintained, applied for or intend to apply for with respect to Boyounuo® (BA1101).

Collaboration arrangements and commercialization plans

To commercialize Boyounuo® (BA1101) in the PRC, we contracted with third party promoters to publicize and maximize the market potential of the product, including AstraZeneca China which promotes Boyounuo® (BA1101) in hospitals located in certain counties or that are otherwise not covered by our in-house sales and marketing team. For more details, see "— Commercialization, sales, marketing and distribution — Third-party promoters" in this section.

Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)

Overview

We are developing BA1102 as an Xgeva® (denosumab) biosimilar under the name of Denosumab Injection. Xgeva® (denosumab as its generic name) is primarily used to treat patients with SRE caused by multiple myeloma and bone metastases from solid tumors as well as GCTB that is unresectable or where surgical resection is likely to result in severe morbidity. Xgeva® is 120 mg of denosumab. We began developing BA1102 in July 2015 and are conducting the Phase 3 clinical trial for bone metastases from solid tumors in China. We expect to complete the Phase 3 clinical trial and to file its BLA with the NMPA in the first quarter of 2023 for the treatment of bone metastases from solid tumors and GCTB, which are the same indications as those approved for Xgeva® in China. We plan to commercialize BA1102 as an affordable alternative to Xgeva® primarily in China. According to the Frost & Sullivan Report, the sales revenue of denosumab market of Xgeva® and its biosimilars in China increased from nil in 2017 to RMB141.0 million in 2021, and is expected to increase to RMB2,836.9 million in 2030, with a CAGR of 39.6% from 2021 to 2030.

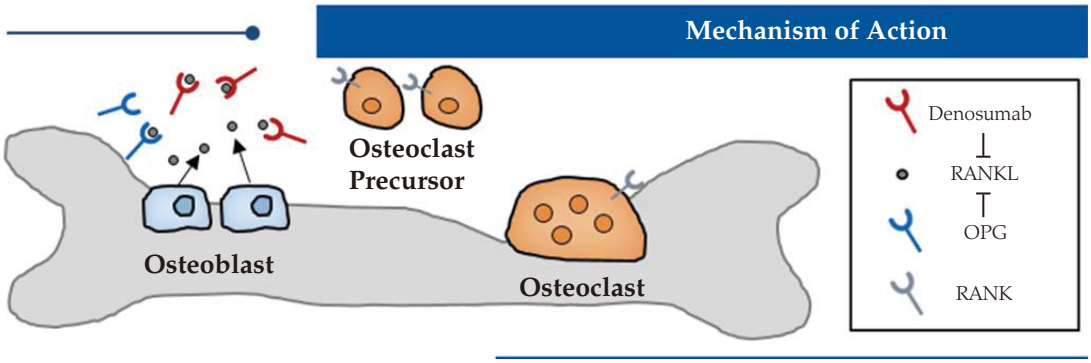
Background of reference drug

Xgeva® (denosumab) is a fully human RANKL IgG2 monoclonal antibody originally developed by Amgen. In November 2010, Xgeva® (denosumab) was first approved for marketing by the FDA and launched in the United States afterwards. In July 2011, it was launched in the EU. In May 2019, Xgeva® was approved by the NMPA to launch in China. Denosumab was first added to the NRDL (2020 edition), effective from March 1, 2021. Major patents for denosumab will expire in the United States in 2025 and in the EU predominantly in 2025. Major patents for denosumab in China have expired in June 2022. In 2021, the global sales of Xgeva® amounted to US$2.2 billion, while the sales in China amounted to RMB141.0 million according to the Frost & Sullivan Report.

Xgeva® has been approved around the world for the following treatments of indications: (i) treatment of adults and skeletally mature adolescents (defined by at least one mature long bone and a weight ≥45 kg) with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; (ii) prevention of SRE caused by bone metastases for solid tumors; (iii) prevention of SREs caused by multiple myeloma and (iv) treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Mechanism of action

Denosumab is a fully human monoclonal antibody that binds with high affinity and specificity to RANKL preventing activation of its receptor, RANK, on the surface of osteoclast precursors and osteoclasts. RANKL, together with its receptor RANK and OPG, is the key mediator in the pathway involved in regulating bone resorption. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone.



Source: Frost & Sullivan Report

Current therapies

The dosage and administration of denosumab vary by indication such as the following examples.

Bone metastases from solid tumors: In addition to specific chemotherapy and targeted therapy for primary tumors, major domestic and foreign guidelines recommend denosumab or bisphosphonates to reduce and delay the occurrence of SREs. Generally, as a first-line therapy for bone metastases from solid tumors, denosumab is administered at 120 mg every four weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen.

GCTB: Denosumab is the only regimen for the treatment of unresectable GCTB or when surgical resection is likely to result in severe morbidity. Denosumab is administered at 120 mg every four weeks with additional 120 mg doses on days eight and 15 of the first month of therapy as a subcutaneous injection in the upper arm, upper thigh, or abdomen.

Potential market opportunities and competition

In recent years, the morbidity and mortality rates of malignant tumors have continued to rise in China. Bones are the most common site of advanced tumor metastases. SREs caused by bone metastases not only lead to reduced physical function and quality of life in patients, but also lead to an increased risk of death. With the continuous improvement of anti-cancer treatment methods, the survival time of patients with advanced cancer continues to increase, and the risk of bone metastases and other skeletal complications also increases significantly. Bone metastasis occurs when cancer cells spread from their original site to a bone. The incidence of bone metastases in advanced malignant tumors is as high as 30%-75%. Nearly all types of cancer can metastasize to the bones. Common tumors prone to bone metastases include solid tumors such as breast cancer (65%-75%), prostate cancer (65%-75%), thyroid cancer (60%), lung cancer (30%-40%), kidney cancer (20%-25%) and malignant melanoma (14%-45%), which provide a wide patient base for denosumab. Global bone metastasis drug market size increased from US$11.7 billion in 2017 to US$16.0 billion in 2021, with a CAGR of 8.2%, and is expected to continue to increase to US$32.3 billion in 2030, with a CAGR of 8.1% from 2021 to 2030. In 2021, the sales revenue of Xgeva® accounted for 13.8% of global bone metastases drug market. China bone metastasis drug market size increased from RMB7.5 billion in 2017 to RMB12.0 billion in 2021, with a CAGR of 12.5%, and is expected to continue to increase to RMB29.8 billion in 2030, with a CAGR of 10.7% from 2021 to 2030. In 2021, the sales revenue of Xgeva® accounted for 1.2% of China bone metastases drug market. According to the label of denosumab, three clinical trials were conducted to test the efficacy and safety of the drug, targeting bone metastasis in breast cancer, NSCLC and prostate cancer respectively. According to the NCCN guideline, denosumab is mostly of category 1 when treating bone metastasis of different types of primary cancer. Category 1 recommendation represents the highest level of recommendation in the guideline due to consensus on evidence. For NCCN guidelines, the recommendation categories are Category 1, Category 2A, Category 2B and Category 3, where Category 1 means that there is uniform NCCN consensus that the intervention is appropriate based upon high-level evidence.

Systemic therapy is the main treatment, among which chemotherapy, endocrine therapy, and molecular targeted therapy are the basic drug treatments for recurrent and metastatic breast cancer, and bisphosphonates can prevent and treat SRE. Reasonable local treatment can better control the symptoms of bone metastases. Surgery is an active means to treat single bone metastases, and radiotherapy is an effective local treatment. A single randomized clinical study suggests that denosumab injections can also be considered for breast cancer patients who require bisphosphonate therapy for bone metastases.

Systemic therapy including chemotherapy, molecular targeted therapy, and immunotherapy can be used as anti-tumor treatments for lung cancer. Reasonable local treatment can better control the symptoms of bone metastases. Surgery is recommended for the treatment of isolated bone metastases, and radiotherapy is also an effective local treatment. Bisphosphonates can prevent and delay the occurrence of SRE. Bone modifiers, including bisphosphonates and denosumab, are suitable for bone metastases.

A multi-disciplinary diagnosis and treatment model should be adopted to formulate diagnosis and treatment strategies. The main treatment methods include drug therapy (endocrine therapy, chemotherapy, targeted therapy, bisphosphonates and denosumab), analgesia therapy, external beam radiotherapy, radionuclide therapy, orthopedic surgery and minimally invasive interventional therapy. Denosumab is superior to zoledronic acid in reducing and delaying the occurrence of SRE in patients with metastatic castration-resistant prostate cancer bone metastases. Common adverse reactions of denosumab include hypocalcemia and osteonecrosis of the mandible.

According to the Frost & Sullivan Report, GCTBs are intermediate malignant bone tumors with high local infiltration ability, which accounts for approximately 5% of all primary bone tumors. More than half of these lesions occur in the third and fourth decades of life. The global incidence of GCTB increased from 11.1 thousand in 2017 to 11.7 thousand in 2021, with a CAGR of 1.4%. It is expected to increase to 13.1 thousand in 2030, with a CAGR of 1.2% from 2021 to 2030. In China, the incidence of GCTB increased from 2.1 thousand in 2017 to 2.1 thousand in 2021, with a CAGR of 0.7%. It is expected to increase to 2.2 thousand in 2030, with a CAGR of 0.6% from 2021 to 2030. Global GCTB drug market size increased from US$90.3 billion in 2017 to US$125.2 billion in 2021, with a CAGR of 8.5%, and is expected to continue to increase to US$199.4 billion in 2030, with a CAGR of 5.3% from 2021 to 2030. In 2021, the sales revenue of Xgeva® accounted for 1.8% of global GCTB drug market. China GCTB drug market size increased from RMB16.5 billion in 2017 to RMB19.6 billion in 2021, with a CAGR of 4.5%, and is expected to continue to increase to RMB38.6 billion in 2030, with a CAGR of 7.8% from 2021 to 2030. In 2021, the sales revenue of Xgeva® accounted for 0.7% of China GCTB drug market. Xgeva® (denosumab) has been included in the 2021 CSCO guideline, making it the first targeted pharmacological treatment of GCTB that was included in the guideline. Xgeva® is class I recommendation for the treatment of unresectable GCTB and class II recommendation for pre-surgical treatment of resectable GCTB. Class I recommendation means evidence and/or general agreement that a given treatment or procedure is beneficial, useful and effective. Class II recommendation means conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.

In addition, Xgeva® is the first, and currently the only, drug for the treatment of GCTB that is unresectable or where surgical resection is likely to result in severe morbidity. It offers patients an innovative treatment option to control disease progression and improve the quality of life. Benefiting from a large patient base with multiple indications, the China denosumab market size of Xgeva® and its biosimilars increased from nil in 2017 to approximately RMB141.0 million in 2021, and is expected to increase to RMB2,836.9 million in 2030, with a CAGR of 39.6% from 2021 to 2030.

For the competitive landscape of marketed denosumab, there was no biosimilar to Xgeva® (denosumab) that had launched in any market as of the Latest Practicable Date. The details of Xgeva® (denosumab) are set forth below:

Brand name	Generic name	Company	Region/authority	Initial approval date	Approved indications	Annual cost per patient	2021 global sales revenue	NRDL
Xgeva® 安加維 (reference drug)	Denosumab	Amgen	U.S./FDA	2010-11-19	• Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. • Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.	~US$34,294.1 (bone metastasis from solid tumors and multiple myeloma) ~US$39,570.2 (GCTB)	US$2.2 billion	-
		Amgen	EU/EMA	2011-07-13	• Prevention of skeletal related events in adults with advanced malignancies involving bone. • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.	~€24,000 (cost varies among countries)		-
		Amgen/ BeiGene	China/NMPA	2019-05-21	• Treatment of adults and skeletally mature adolescents (defined by at least one mature long bone and a weight ≥ 45 kg) with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. • Skeletal-related events in patients with bone metastases from solid tumors. • Skeletal-related events in patients with multiple myeloma.	~RMB13,780 (bone metastases from solid tumor and multiple myeloma) ~RMB15,900 (GCTB)		Category B[2]

Note:

(1) The median duration of treatment of Xgeva® is 12 months based on disclosure on FDA label, but the length of treatment for a patient is dependent on disease status and patient condition and is subject to physician discretion.

(2) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

Source: Frost & Sullivan Report

Globally (outside of China), there were two clinical-stage Xgeva® (denosumab) biosimilar candidates as of the Latest Practicable Date. In China, there were six clinical-stage Xgeva® (denosumab) biosimilar candidates as of the same date. The details are set forth below:

Region	Drug name/code	Company	Phase	Indications	First posted date
China	**BA1102**	**Our Group**	**Phase 3**	**Bone metastases from solid tumors**	**2021-02-08**
	9MW0321	Jiangsu T-mab Bio-Pharma	BLA	Prevent skeletal-related events caused by bone metastases from solid tumors	2021-12-22
	QL1206	Qilu Pharma	BLA	Bone metastases from solid tumors	2021-08-30
	HS629	Hisun Pharma	Phase 1	Prevent skeletal-related events caused by bone metastases from solid tumors	2018-04-12
	HL05	Hualan Genetic	Phase 1	Prevent skeletal-related events caused by bone metastases from solid tumors	2020-02-26
	HS-20090	Jiangsu Hansoh Pharmaceutical/ Shanghai Hansoh BioMedical	Phase 3	Prevent skeletal-related events caused by bone metastases from solid tumors and multiple myeloma	2022-10-21
Europe	**BA1102[1]**	**Our Group**	**Phase 1**	**Bone metastases from solid tumors, GCTB**	**2020-10-20**
	MB09	mAbxience S.A	Phase 1	Healthy male	2022-03-28

Note:

(1) BA1102 is in the stage of Phase 1 clinical trial in the EU by virtue of the clinical trial conducted for BA6101 in the EU. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phase 1 and Phase 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®.

(2) For overseas biosimilars to enter the China market, data from overseas clinical trials can be accepted for BLA since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018.

Source: Frost & Sullivan Report

Denosumab was included in the NRDL (2020 edition), effective from March 1, 2021, and the price dropped to RMB1,060 from RMB5,298. This will pose challenges for the pricing and market share of BA1102 after its future commercialization. We expect the inclusion of the NRDL will promote the market penetration of denosumab, which will benefit BA1102's future commercialization.

BA1102 is potentially one of the three first-to-market biosimilar drugs in China targeting bone metastases from solid tumors and GCTB and we aim to become the early-mover to occupy market share ahead of other competitors in China, which generally is less susceptible to price competition from competitors falling behind on their product launch. We believe BA1102 will be well positioned to compete in the market and gain a leading market share following its launch.

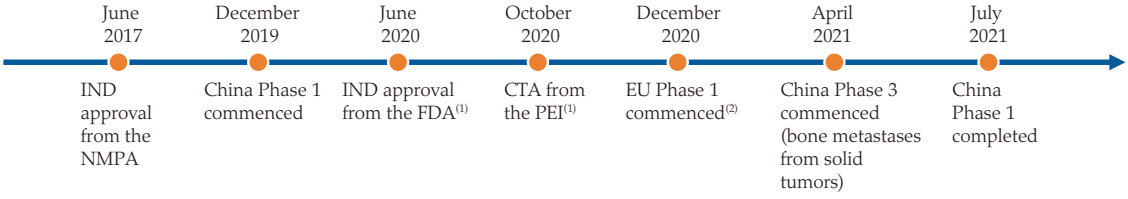
Summary of clinical development history and results

As of the Latest Practicable Date, we were conducting a multi-center Phase 3 clinical trial for BA1102 in China and we had completed the Phase 1 clinical trial in China. Based on the data collected and analyzed in the Phase 1 clinical trial, we concluded that a single dose of BA1102 or Xgeva® by subcutaneous injection in healthy subjects was bioequivalent, with similar PK and PD profiles. They show good overall safety and tolerability, and similar immunogenicity and safety profiles.

Because BA1102 and BA6101 contain the same active agent, denosumab, and have the same mechanism of action, we communicated the development strategies of BA1102 and BA6101 with the EMA in April 2019 and with the FDA in October 2019. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phases 1 and 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®. BA1102 is in the stage of Phase 1 clinical trial in the EU, by virtue of the clinical trial we are conducting for BA6101.

Clinical development

The chart below summarizes the development timeline of BA1102:



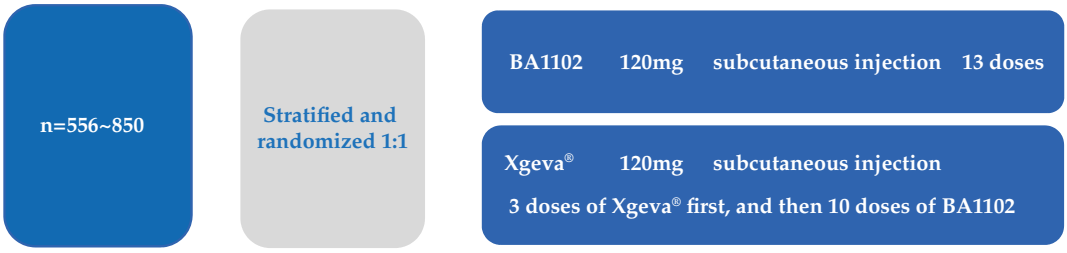
Notes:

(1) As the results of Phases 1 and 3 clinical trials of BA6101 will support the extrapolation of its indications to all indications of Prolia® and Xgeva® in the United States and the EU, the IND approval and the CTA were obtained for BA6101.

(2) As the results of Phases 1 and 3 clinical trials of BA6101 will support the extrapolation of its indications to all indications of Prolia® and Xgeva®, BA1102 is in the stage of Phase 1 clinical trial in the EU, by virtue of the clinical trial we are conducting for BA6101.

Ongoing Phase 3 clinical trial

Study design. The ongoing Phase 3 clinical trial is a multi-center, randomized, double-blind, parallel, active-controlled study, comparing the efficacy and safety of BA1102 and Xgeva® patients with bone metastases from solid tumors. It is expected to enroll about 556-850 subjects, who will be randomly divided into two groups in a 1:1 ratio, with each group having about 278-425 subjects. The clinical trial will involve about 62 clinical study centers in China. The BA1102 group will receive 13 doses of BA1102. The Xgeva® group will first receive three doses of Xgeva®, and then 10 doses of BA1102. The dosage for each group will be 120 mg. The trial will continue for 53 weeks.



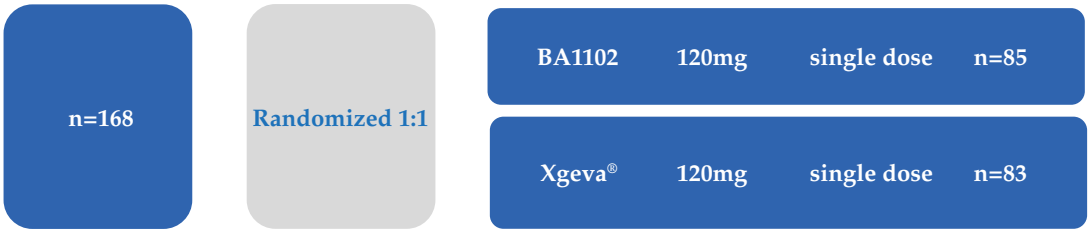
The primary endpoint is the natural logarithm change from baseline to week 13 in bone turnover marker – urinary type I collagen cross-linked N-telopeptides ("**uNTx**") corrected for urine creatinine ("**uCr**").

The secondary endpoints include: (i) time to first on-study SRE; (ii) incidence of SRE; (iii) percent change of serum bone-specific alkaline phosphatase from baseline to weeks 13, 25, and 53; and (iv) natural logarithm change in uNTx/uCr from baseline to weeks 25 and 53.

Safety and efficacy. As of the Latest Practicable Date, the Phase 3 clinical trial for the treatment of bone metastases from solid tumors was ongoing, and thus safety and efficacy findings were not yet available.

Phase 1 clinical trial

Study design. The Phase 1 clinical trial was a single-center, randomized, double-blind, parallel-controlled, single-dose study, comparing the pharmacokinetics, pharmacodynamics, safety, tolerability and immunogenicity of BA1102 and Xgeva® at 120 mg in healthy adult subjects. The Phase 1 clinical trial was completed in July 2021. 168 subjects were enrolled and divided into two groups. One group of 85 subjects received a single dose of BA1102 and the other group of 83 subjects received a single dose of Xgeva®, both at 120 mg. The trial continued for about 252 days.



The primary endpoints were the C_{max} and the AUC_{0-t}.

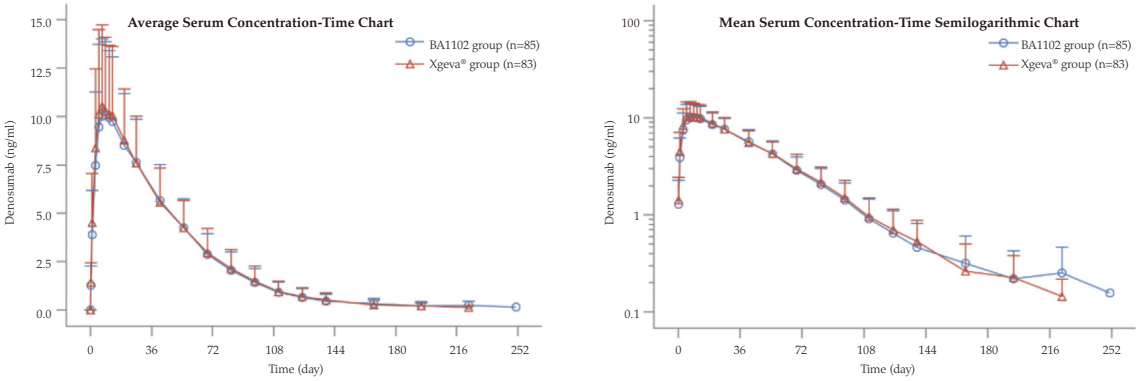
The secondary PK endpoints included observations of (i) $AUC_{0-\infty}$; (ii) T_{max}; (iii) apparent total body clearance ("**CL/F**"); (iv) elimination rate constant ("λ_z"); (v) $t_{1/2}$; and (vi) apparent volume of distribution ("$\mathbf{V_d/F}$").

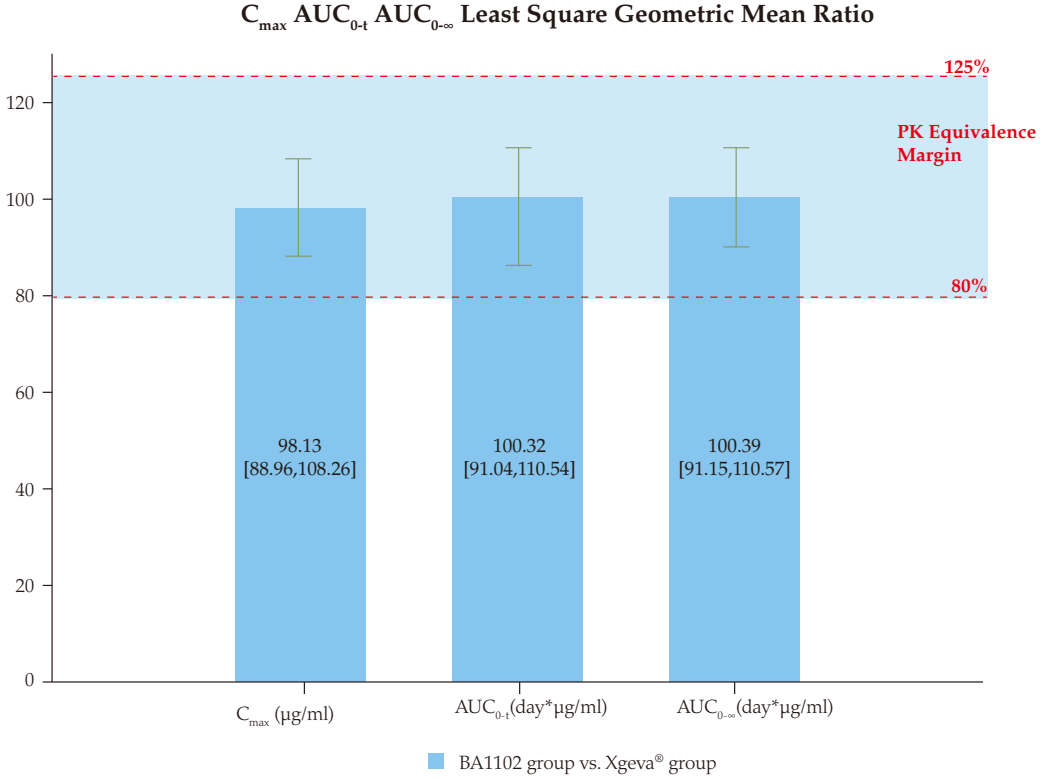
The PD endpoints included (i) changes in serum collagen type I C-telopeptide ("**CTX-1**"); (ii) area under the effect curve ("$\mathbf{AUEC_{0-t}}$"); (iii) maximal effect ("$\mathbf{E_{max}}$"); and (iv) time to reach maximum effect ("$\mathbf{TE_{max}}$").

The safety parameters included any adverse event that occurred during the clinical study, and clinical symptoms, abnormal vital signs and physical examinations, as well as abnormal clinical laboratory test values.

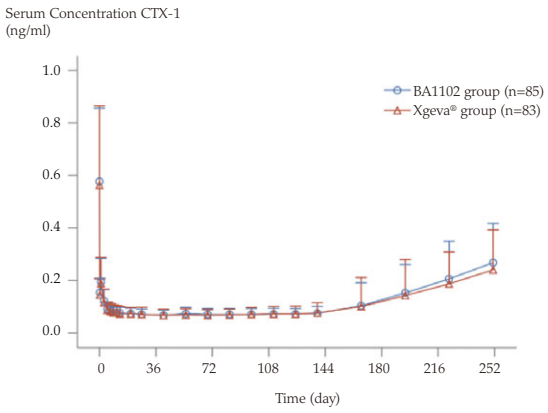
Immunogenicity was also evaluated based on the incidence of ADA-positive results and NAb-positive results.

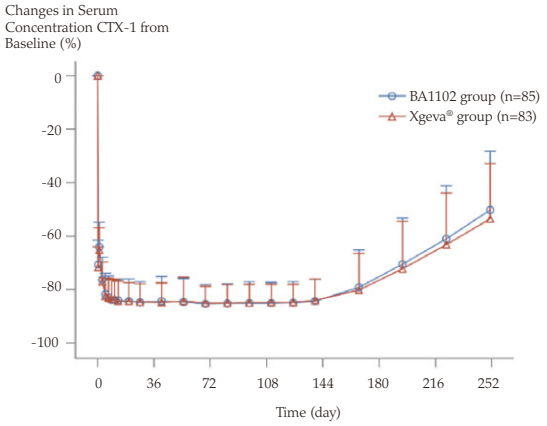
PK. After a single dose of 120 mg BA1102 or Xgeva® by subcutaneous injection, the drug-time curves of the two experimental groups were very similar. The geometric mean ratios of C_{max}, AUC_{0-t} and $AUC_{0-\infty}$ and their 90% CIs of the two groups were all within the equivalence margin range of 80.00%-125.00%, and PK equivalence was achieved. The following diagrams set out the findings in more detail:





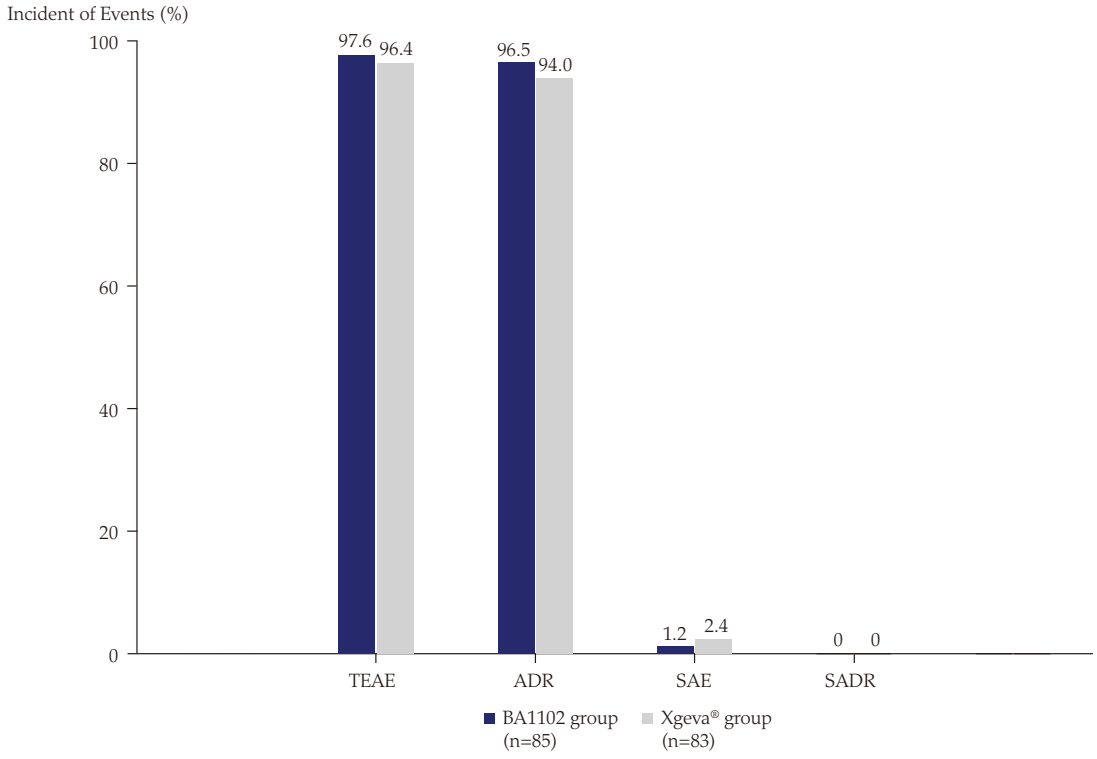
PD. After a single dose of 120 mg BA1102 or Xgeva® by subcutaneous injection, the mean pharmacodynamic-time curve trends of measured serum CTX-1 values and the reduction in serum CTX-1 concentrations of the two experimental groups were very similar. The geometric mean ratios of $AUEC_{0-t}$ and E_{max} and their 90% CI of both groups were within the marginal range of 80.00% to 125.00%. The following diagrams set out the findings in more detail:





Parameters	Geometric mean BA1102	Geometric mean Xgeva®	Geometric ratio (BA1102/Xgeva®)	90% CI (BA1102/Xgeva®)
$AUEC_{0-t}$(day*%)	–19134.77	–19384.79	98.71%	95.48%~102.05%
E_{max}(%)	–87.44	–87.62	99.80%	98.08%~101.54%

Safety. There was no statistically significant difference in the incidence and severity of adverse events between BA1102 and Xgeva®. The incidence rate of TEAEs was 97.6% and 96.4% in the BA1102 and Xgeva® groups, respectively. The incidence rate of ADRs was 96.5% and 94.0% in the BA1102 and Xgeva® groups, respectively. The severity of TEAEs was mainly grade 1, and grade 3 or above TEAEs occurred in three subjects of the BA1102 group and in three subjects of Xgeva® groups, respectively. But these grade 3 or above TEAEs were determined to be possibly/definitely unrelated to the experimental drug. Serious adverse events occurred in one subject of the BA1102 group and two subjects of the Xgeva® group. These SAEs led to withdrawal from the trial but were determined to be possibly/definitely unrelated to the experimental drug. During the course of the trial, no deaths or other serious adverse events related to the studied drug occurred post-treatment. The following diagram sets forth the safety findings in more detail:



SADR: serious study drug-related TEAE

Immunogenicity. Immunogenicity findings also showed no statistically significant difference. No subject was tested positive for ADA within 252 days after injection of BA1102. Although one subject was tested positive for ADA after injection of Xgeva®, he was tested negative for ADA later. No subject was tested positive for NAb before and after injection of BA1102 or Xgeva®.

Pre-clinical research

Because BA1102 and BA6101 contain the same active agent, denosumab, and have the same mechanism of action, we have performed pre-clinical studies of BA6101 including pharmacokinetic and toxicokinetic studies and molecular pharmacology, pharmacodynamics, immunogenicity and toxicity comparison studies in China. For more details, see "— Our Biosimilar Portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®) — Summary of clinical development history and results — Pre-clinical research" in this section.

R&D plan in the United States and the EU

Bone metastasis occurs when cancer cells spread from their original site to a bone. The incidence of bone metastases in advanced malignant tumors is as high as 30%–75%. Nearly all types of cancer can metastasize to the bones. Common tumors prone to bone metastases include solid tumors such as breast cancer (65%–75%), prostate cancer (65%–75%), thyroid cancer (60%), lung cancer (30%–40%), kidney cancer (20%–25%) and malignant melanoma (14%–45%), which provide a wide patient base for denosumab. Global bone metastasis drug market size increased from US$11.7 billion in 2017 to US$16.0 billion in 2021, with a CAGR of 8.2%, and is expected to continue to increase to US$32.3 billion in 2030, with a CAGR of 8.1% from 2021 to 2030. According to the Frost & Sullivan Report, the global incidence of GCTB increased from 11.1 thousand in 2017 to 11.7 thousand in 2021, with a CAGR of 1.4%. It is expected to increase to 13.1 thousand in 2030, with a CAGR of 1.2% from 2021 to 2030. Global GCTB drug market size increased from US$90.3 billion in 2017 to US$125.2 billion in 2021, with a CAGR of 8.5%, and is expected to continue to increase to US$199.4 billion in 2030, with a CAGR of 5.3% from 2021 to 2030. The global denosumab market size of Xgeva® and its biosimilars increased from US$1,708.8 million in 2017 to approximately US$2,203.8 million in 2021, with a CAGR of 6.6%, and is expected to decrease to US$1,824.6 million in 2030. As the United States and the EU markets contribute to a large portion of the global market, we decide to commercialize BA1102 in the United States and the EU. In addition, in the United States, the annual cost of Xgeva® for 2021 was approximately US$34,294.1 per person for patients with bone metastasis from solid tumors and multiple myeloma and US$39,570.2 per person for patients with GCTB. In the EU, the annual cost of Xgeva® for 2021 was approximately €24,000 per patient, which varies among the counties in the EU. In China, the annual cost of Xgeva® for 2021 was approximately RMB13,780 per person for patients with bone metastasis from solid tumors and multiple myeloma and RMB15,900 per person for patients with GCTB. Similarly, as advised by Frost & Sullivan, the pricing of biosimilars in the United States and EU are also higher than their pricing in China. Therefore, Xgeva®'s pricing in the United States and the EU including its biosimilars' is more advantageous and entails higher profit margin, which make it easier for us to recover our upfront R&D investment.

For details of the R&D plans, regulatory framework and timeline for us to obtain market registration approval in the United States and the EU for BA1102 and BA6101, see "— Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®) — R&D plan in the United States and the EU" in this section.

BA1102 in the EU will be regarded as a medicinal product which is similar to a biological medicine, also known as the "reference medicine", that is already authorized in the EU. The legal basis for applications for such biosimilar medicinal products is Art. 10(4) of Directive 2001/83/EC which is implemented in the respective national legislation of each member state of the EU. BA1102 in the United States will be classified as a biosimilar product under the section 351(k) of the Public Health Service Act.

Material communications and next steps

Material communications with the NMPA/CDE

Our BA1102 has completed at least one clinical trial conducted on human subjects. The NMPA and the CDE, which are the relevant competent authorities, have no objection for us to commence the Phase 3 clinical trial to demonstrate bio-equivalency. We set forth below the key regulatory milestones, including material communications with the NMPA and the CDE, in developing BA1102.

IND approval

We received the IND approval from the CDE in June 2017, which permitted us to commence clinical trials, including both Phase 1 and Phase 3 clinical trials. In particular, the IND approval did not contain any condition for us to commence the Phase 1 and Phase 3 clinical trials or require us to complete or reach any main point of the Phase 1 clinical trial before commencing the Phase 3 clinical trial.

According to our PRC Legal Adviser, we have obtained all necessary approvals from the NMPA and the CDE to proceed with the BA1102 clinical trials including the Phase 1 and Phase 3 clinical trials, and the NMPA and the CDE has no objection for us to commence the Phase 3 clinical trial as planned.

Phase 1 clinical trial

We commenced the BA1102 Phase 1 clinical trial in December 2019 in China, which was completed in July 2021. The Phase 1 clinical trial was a single-center, randomized, double-blind, parallel-controlled, single-dose study, comparing the pharmacokinetics, pharmacodynamics, safety, tolerability and immunogenicity of BA1102 and Xgeva® at 120 mg in healthy adult subjects.

Phase 3 clinical trial

On April 21, 2020, we had communications with the CDE in a conference call (the "**2020 April Call**") in relation to initiating the Phase 3 clinical trial and seeking their advice on the clinical trial design, during which it had no objection for us to initiate the Phase 3 clinical trial once we revised the clinical trial design as requested. We set forth below details of the material communications with the CDE leading to the commencement of the BA1102's Phase 3 clinical trial.

In February 2020, we were conducting the Phase 1 clinical trial of BA1102 (which was subsequently completed in July 2021) while the Phase 1a clinical trial of BA6101 had already been completed in May 2019. The Phase 1a clinical trial of BA6101 included the 18 mg denosumab dose group, the 60 mg denosumab dose group and the 120 mg denosumab dose group, the results of which demonstrated that a single subcutaneous injection of BA6101 (with 18 mg, 60 mg and 120 mg dose, respectively) was safe and well tolerated in healthy subjects. Among the three dose groups, 120 mg is the same dose of BA1102 (120 mg denosumab), and therefore the Phase 1a clinical trial results of BA6101 was a reference for the safety of BA1102. See "— Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®) — Summary of clinical development history and results — Phase 1a clinical trial in China" in this section for more details of the Phase 1a clinical trial of BA6101. On February 11, 2020, we submitted a formal meeting request with the CDE for Phase 3 clinical trial of BA1102. The 2020 April Call was subsequently held on April 21, 2020. During the call, for purposes of discussing the Phase 3 clinical trial design of BA1102 in China, we shared with the CDE (i) our communication experience with relevant competent authorities of the EU and the US; and (ii) the Phase 1a clinical trial results of BA6101 (because BA1102 and BA6101 contain the same active agent, denosumab, and have the same mechanism of action, the clinical trial results of BA6101 is of high reference value to the clinical trial development of BA1102), as a reference for the safety of BA1102. The CDE, after receiving our briefing, was fully aware of our reference to Phase 1a clinical trial results of BA6101 and requested on the same conference call to extend the observation period of the PK similarity study of BA1102 and Xgeva® from six months to nine months according to the EU and the US development requirement. Based on the above communications with the CDE, we finalized the Phase 3 clinical trial design for BA1102. Subsequently, based on the above revised clinical trial design according to the request of the CDE and the Phase 1a clinical results of BA6101 (which contains the same active agent, denosumab, and has the same mechanism of action as BA1102), in December 2020 we obtained the approval from the ethics committee of the hospital responsible for conducting BA1102's Phase 3 clinical trial, and in April 2021 we commenced the Phase 3 clinical trial of BA1102 for bone metastases from solid tumors in China.

Through our CDE drug clinical trial registration published on February 8, 2021 and our communications with the CDE as set forth above, the CDE was fully aware of BA1102's clinical trial development plan and the revised clinical trial design of the Phase 3 clinical trial and had no objection for us to commence the Phase 3 clinical trial. Our PRC Legal Adviser has confirmed that there are no laws or regulations requiring any further affirmative confirmation from the CDE to approve the commencement of Phase 3 clinical trial after the 2020 April Call with the CDE on the Phase 3 clinical trial and the CDE has no objection for us to commence the Phase 3 clinical trial. In addition, as confirmed by Frost & Sullivan, the above arrangements between us and the CDE are in line with the industry norm.

Other than the above, we have not had any material regulatory communications with the NMPA or the CDE for BA1102, and we are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA1102.

We continue to conduct our Phase 3 clinical trial of BA1102 for the bone metastases from solid tumors indications, and plan to file the BLA to the CDE in the first quarter of 2023 and expect to receive regulatory approval to commence commercialization in the first quarter of 2024.

We will file the BLA for the indications of bone metastases from solid tumors and GCTB that is unresectable or where surgical resection is likely to result in severe morbidity. According to the Technical Guidelines for Research, Development and Evaluation of Biosimilars (《生物類似藥研發與評價技術指導原則》) and Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》, on the basis of the biosimilarity established between the proposed product and reference product through totality-of-the-evidence approach, if the clinical similarity is confirmed in at least an appropriate indication, the applicant may seek licensure of the proposed product for one or more additional indications for which the reference product is licensed. At present, the reference drug of BA1102, i.e., Xgeva®, was approved in China for treating bone metastases from solid tumors, and GCTB that is unresectable or where surgical resection is likely to result in severe morbidity. If the results of the clinical trial of BA1102 demonstrate the biosimilarity in the indication of treating bone metastases from solid tumors, we expect to extrapolate the indications of BA1102 to GCTB that is unresectable or where surgical resection is likely to result in severe morbidity, without the need for a completed clinical trial for GCTB.

BA1102 and BA6101 were developed as separate product candidates rather than as expansion of indications of each other. The NMPA will issue two separate market registration certificates upon approval for BA6101 and BA1102 even though they share the same active agent (denosumab) and have the same mechanism of actions.

See "— Intellectual property" for details of intellectual properties which we have registered, maintained, applied for or intend to apply for with respect to BA1102.

Material communications with the PEI, the EMA and the FDA

Because BA1102 and BA6101 contain the same active agent, denosumab, and have the same mechanism of action, we communicated the development strategies of BA1102 and BA6101 with the EMA in April 2019 and with the FDA in October 2019. For more details, see "— Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®) — Summary of clinical development history and results" and "— Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®) — Material communications and next steps" in this section. Other than the above, we have not had any material regulatory communications with the PEI, the EMA or the FDA for BA1102, and we are not aware of any material concern from the PEI, the EMA or the FDA in connection with our ongoing development of BA1102.

Collaboration arrangements and commercialization plans

We intend to manufacture BA1102, once approved, at our Yantai Site for distribution in China. See " — Manufacturing" in this section for further details on the technologies utilized in the Yantai Site. Our marketing efforts will primarily target relevant hospitals across China leveraging our dedicated in-house sales and marketing team and our distribution network of Boyounuo® (BA1101). We will also explore collaboration arrangements with promoters and other distributors to commercialize BA1102 in China. In addition, we will explore the possibility of expanding the commercialization of BA1102 to overseas markets.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA1102.

Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)

Overview

We developed BA6101 as a Prolia® (denosumab) biosimilar. Prolia® (denosumab as its generic name) is primarily used for the treatment of postmenopausal women with osteoporosis at high risk for fracture, treatment to increase bone mass in men with osteoporosis at high risk for fracture, treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Prolia® is 60 mg of denosumab. We began developing BA6101 in November 2014 and have completed the Phase 3 clinical trial for treating postmenopausal women with osteoporosis at high risk for fracture and have submitted the BLA to the NMPA afterwards. The NMPA has accepted our BLA in October 2021. We received the regulatory approval to commence commercialization of BA6101 in November 2022 in China. In addition, the FDA and the PEI have approved our IND application and CTA in June 2020 and October 2020, respectively, and we are conducting Phase 1 clinical trial in the EU. We publishing three papers in *Frontiers in Pharmacology*, *Expert Opinion on Investigational Drugs* and *Journal of Orthopaedic Translation*, covering the clinical trial results of BA6101.

Background of reference drug

Prolia® (denosumab) is a fully human RANKL IgG2 monoclonal antibody originally developed by Amgen. It was approved by the FDA in 2010 under the trade name Prolia® for treating postmenopausal women with osteoporosis at high risk for fracture and launched in the United States afterwards. It was also approved by the EMA in the same year under the same trade name for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures, and the treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture. Prolia® was approved by the NMPA for treating postmenopausal women with osteoporosis at high risk for fracture in 2020. Denosumab was first included in the NRDL (2020 edition), effective from March 1, 2021. It is the first, and currently the only, anti-RANKL monoclonal antibody for treating osteoporosis in China. In postmenopausal women, Prolia® significantly reduces the risk of vertebral, non-vertebral and hip fractures. It brought opportunities to improve bone health management and quality of life for patients. Major patents for denosumab will expire in the United States in 2025 and in the EU predominantly in 2025. Major patents for denosumab in China have expired in June 2022. In 2021, the global sales of Prolia® amounted to US$3.6 billion according to the Frost & Sullivan Report.

Prolia® has been approved around the world for the following indications: (i) treatment of postmenopausal women with osteoporosis at high risk for fracture; (ii) treatment to increase bone mass in men with osteoporosis at high risk for fracture; (iii) treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture; (iv) treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and (v) treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Mechanism of action

Denosumab is a fully human monoclonal antibody that binds RANKL, preventing RANKL from activating RANK, its receptor on the osteoclast surface. See "— Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®) — Mechanism of action" in this section for further details.

Current therapies

The common first-line treatment of postmenopausal women with osteoporosis at high risk for fracture is bisphosphonates. FDA-approved indications for bisphosphonates include treatment of osteoporosis in postmenopausal women, osteoporosis in men, glucocorticoid-induced osteoporosis, hypercalcemia of malignancy, Paget's disease of the bone, and malignancies with metastasis to the bone. Prolia® is the first and only RANKL inhibitor for osteoporosis in China and is recommended in the "Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis". Multiple studies to date have shown that, RANKL inhibitors can significantly increase the bone mineral density of the lumbar spine, hip and femoral neck and reduce the risk of fracture. Treatment for men with osteoporosis at high risk for fracture, glucocorticoid-induced osteoporosis in men and women at high risk for fracture, as well as treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, are similar to first-line therapy for postmenopausal women with osteoporosis at high risk for fracture, also including bisphosphonates and RANKL inhibitors. Denosumab treatment requires subcutaneous injection, 60 mg every six months, and patients need 1,000 mg calcium and 400 IU vitamin D supplementation daily during treatment.

Potential market opportunities and competition

According to the Frost & Sullivan Report, based on a comprehensive systemic review and meta-analysis published in 2021, the overall global prevalence of osteoporosis in the elderly women was 35.3% and in the elderly men was 12.5%. The prevalence of osteoporosis in Asia, Europe, and the United States was 24.3%, 16.7%, and 11.5%, respectively, with the highest prevalence in Asia. The world's aging population is experiencing growth in terms of both number and proportion. According to data from the World Bank, the global population aged over 65 years increased from 650.0 million (8.7% of the total population) in 2017 to 748.1 million (9.6% of the total population) in 2021, and is expected to reach approximately 990.5 million (11.7% of the total population) in 2030.

Declining fertility and increasing longevity are the key drivers of population aging globally. Global osteoporosis drug market size increased from US$13.2 billion in 2017 to US$16.8 billion in 2021, with a CAGR of 6.2%, and is expected to continue to increase to US$27.6 billion in 2030, with a CAGR of 5.7% from 2021 to 2030. In 2021, the sales revenue of Prolia® accounted for 21.4% of global osteoporosis drug market.

According to the China Osteoporosis Prevalence Study conducted between 2017 and 2018 and published in 2021, 5.0% of men and 20.6% of women aged 40 years or above had osteoporosis in China. Osteoporosis is a common and preventable disorder that predisposes an individual to an increased risk of fracture, a major cause of disability in older adults. The most common locations for osteoporosis-related fractures are in the hip, spine, and wrist, and serious hip, spine, and wrist fractures often require surgical intervention, which results in a decline in health-related quality of life. Osteoporosis increases with age. According to the Frost & Sullivan Report, the population of the elderly over 65 years old in China increased from 158.3 million (11.4% of the total population) in 2017 to 200.6 million (14.2% of the total population) in 2021, and is expected to reach approximately 317.6 million (22.0% of the total population) by 2030. China osteoporosis drug market size increased from RMB19.4 billion in 2017 to RMB27.6 billion in 2021, with a CAGR of 9.3%, and is expected to continue to increase to RMB50.8 billion in 2030, with a CAGR of 7.0% from 2021 to 2030. In 2021, the sales revenue of Prolia® accounted for 0.8% of China osteoporosis drug market.

Two categories of osteoporosis have been identified: primary and secondary. Primary osteoporosis is the most common form of the disease and includes postmenopausal osteoporosis (type I), and senile osteoporosis (type II). In postmenopausal women, the decrease in estrogen levels causes bone resorption rates to be greater than bone formation rates. While the disease process of osteoporosis is silent, the loss of bone strength increases the risk of fractures. Osteoporotic fractures typically occur at the hip, distal forearm, spine or proximal humerus, and fractures of the hip and spine are associated with increased morbidity and mortality. A number of factors can increase the likelihood of developing osteoporosis, including age, race, lifestyle choices, and medical conditions and treatments. Choice of prevention and treatment of osteoporosis in postmenopausal women should take effectiveness, risk and economic cost into consideration. Patients with low or medium risk should take actions to maintain bone health including adopting a healthy lifestyle and getting enough calcium and Vitamins D. At the same time, Hormone Therapy ("**HT**") can be used. Women with a high risk of fracture should take anti-osteoporosis medications.

In 2010, Prolia® was approved by the FDA for the treatment of postmenopausal women with osteoporosis at high risk for fracture. A pivotal Phase 3 clinical trial of 7,808 postmenopausal patients with osteoporosis showed that the bone mineral density of postmenopausal patients with osteoporosis continued to increase within 10 years, showing good long-term drug efficacy and safety. Patients with renal insufficiency can also take the drug normally without dose adjustment. Under the combined effects of various factors such as a large patient group, favorable clinical results and no serious adverse reactions, Prolia® quickly occupied a significant share in a broad market.

According to the Frost & Sullivan Report, the global denosumab market size of Prolia® and its biosimilars increased from US$2,164.2 million in 2017 to US$3,593.1 million in 2021, with a CAGR of 13.5%, and is expected to increase to US$3,984.7 million in 2030, with a CAGR of 1.2% from 2021 to 2030. In June 2020, Prolia® was approved for osteoporosis indications in China. Benefiting from a large patient base with multiple indications, the sales revenue of denosumab market of Prolia® and its biosimilars in China in 2021 was RMB210.1 million and is expected to increase to RMB7,823.7 million in 2030, with a CAGR of 49.5%.

For the competitive landscape of BA6101 marketed denosumab, BA6101 was the only Prolia® (denosumab) biosimilar approved in China as of the Latest Practicable Date. The details of Prolia® (denosumab) and BA6101 are set forth below:

Brand name	Generic name	Company	Region/authority	Initial approval date	Approved indications	Annual cost per patient	2021 global sales revenue	NRDL
Prolia® 普羅力 (reference drug)	Denosumab	Amgen	U.S./FDA	2010-06-01	• Treatment of postmenopausal women with osteoporosis at high risk for fracture • Treatment to increase bone mass in men with osteoporosis at high risk for fracture • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	~US$2,868.3	US$3.6 Billion	-
		Amgen	EU/EMA	2010-05-26	• Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures • Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures • Treatment of bone loss associated with long-term systemic glucocorticoid therapy in audit patients at increased risk of fracture	NA		-
		Amgen	China/NMPA	2020-06-17	• Treatment of postmenopausal women with osteoporosis at high fracture risk	~RMB1,247.1		Category B[1]
博优倍®		**Our Group**	**China/NMPA**	**2022-11-08**	• **Treatment of postmenopausal women with osteoporosis at high fracture risk**	**NA**	**NA**	**Category B[1]**

Note:

(1) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

(2) NA means public information is not available.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, globally (outside of China), there were 11 clinical-stage Prolia® (denosumab) biosimilar candidates, the details of which are set forth below:

Drug name/code	Company	Region	Phase	Indications	First posted date
BA6101	**Our Group**	**Europe**	**Phase 1**	**Osteoporosis**	**2020-10-20**
GP2411	Sandoz	US, Europe, Japan	Phase 3	Postmenopausal osteoporosis	2019-06-04
SB16	Samsung Bioepis	Poland	Phase 3	Postmenopausal osteoporosis	2020-12-11
TVB-009	Teva Pharmaceuticals	US	Phase 3	Postmenopausal osteoporosis	2021-01-28
CT-P41	Celltrion	Europe	Phase 3	Postmenopausal osteoporosis	2021-02-17
FKS518	Fresenius Kabi SwissBioSim GmbH	Europe	Phase 3	Postmenopausal osteoporosis	2021-06-22
RGB-14-P	Gedeon Richter Plc.	US, Europe	Phase 3	Postmenopausal osteoporosis	2021-10-21
MB09	mAbxience S.A	Europe, Mexico	Phase 3	Postmenopausal osteoporosis	2022-04-20
AVT03	Alvotech Swiss AG	South Africa	Phase 3	Postmenopausal osteoporosis	2022-05-27
ENZ215	Enzene	Czechia	Phase 3	Postmenopausal osteoporosis	2022-06-06
INTP23	Lambda Therapeutics	India	Phase 3	Postmenopausal osteoporosis	2022-06-15

Note:

(1) For overseas biosimilars to enter the China market, data from overseas clinical trials can be accepted for BLA since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018.

Source: Frost & Sullivan Report

Similarly, as of the Latest Practicable Date, there were a number of clinical-stage Prolia® (denosumab) biosimilar candidates in China, the details of which are set forth below:

Drug name/code	Company	Phase	Indications	First posted date
QL1206	Qilu Pharma	BLA	Postmenopausal osteoporosis with high fracture risk	2021-09-06
9MW0311	Jiangsu T-mab Bio-Pharma	BLA	Postmenopausal osteoporosis	2021-12-22
KN012	Suzhou Alphamab | Feiyang Biotech	Phase 3	Postmenopausal osteoporosis with high fracture risk	2020-07-31
CMAB807	Shanghai Biomabs Pharma | Shanghai MabLab Biotech	Phase 3	Postmenopausal osteoporosis with high fracture risk	2020-11-17
HLX14	Henlius Biotech	Phase 3	Postmenopausal osteoporosis with high fracture risk	2022-03-18
MV088	KPC Pharma	Phase 1	Postmenopausal osteoporosis with high fracture risk	2020-11-27
HS-20090-2	Shanghai Hansoh Biomedical	Phase 1	Postmenopausal osteoporosis with high fracture risk	2021-07-16

Source: Frost & Sullivan Report

BA6101 is a potential first-to-market biosimilar drug in China targeting postmenopausal women with osteoporosis at high risk for fracture and we aim to become the early-mover to occupy market share ahead of other competitors in China, which generally is less susceptible to price competition from competitors falling behind on their product launch. We received the regulatory approval to commence commercialization of BA6101 in November 2022 in China. We believe BA6101 will be well positioned to compete in the market and gain a leading market share following its launch.

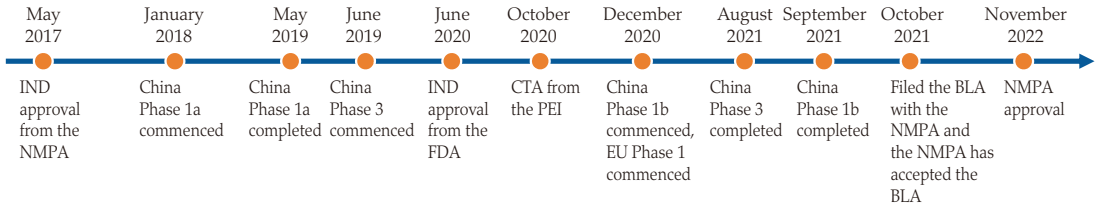
Summary of clinical development history and results

As of the Latest Practicable Date, we had completed the Phase 3 clinical trial of BA6101 for the treatment of postmenopausal women with osteoporosis at high risk for fracture and had received the regulatory approval to commence commercialization in November 2022 in China. Based on the data collected and analyzed, we concluded that in the Phase 3 clinical trial of BA6101, subcutaneous injection of BA6101 every six months significantly increased the lumbar spine, hip, femoral neck, and trochanter BMD and decreased bone turnover markers S-CTX and P1NP in postmenopausal women with osteoporosis at high risk of fracture, compared with placebo. BA6101 was generally safe and well tolerated, and no unexpected adverse reactions occurred. Efficacy and safety profiles were similar compared to previous studies of the reference drug, Prolia®.

Based on the data collected and analyzed in the Phase 1b clinical trial which is a standalone clinical trial, we concluded that a single dose of BA6101 or Prolia® by subcutaneous injection in healthy adult male subjects was bioequivalent, with similar PK and PD profiles. They show good overall safety and tolerability, and similar immunogenicity and safety profiles. Based on the data collected and analyzed in the Phase 1a clinical trial, the single-dose subcutaneous injection of BA6101 (18mg, 60 mg and120 mg) showed good overall safety and tolerability in healthy subjects.

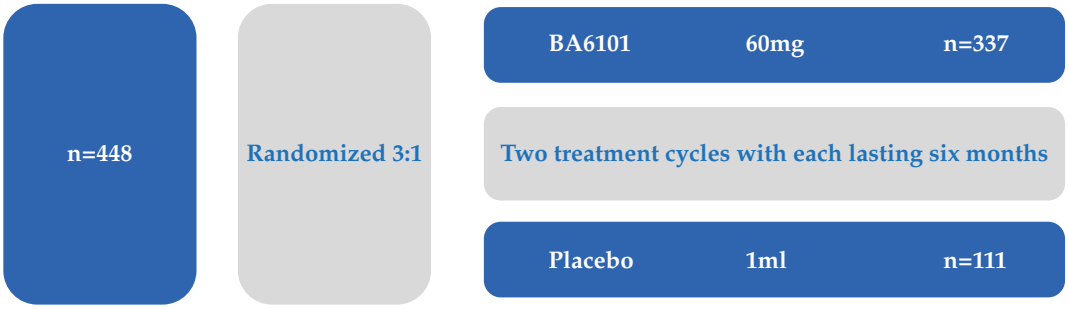
Clinical development

The chart below summarizes the development timeline of BA6101:



Phase 3 clinical trial

Study design. The Phase 3 clinical trial was a multi-center, randomized, double-blind, placebo-controlled, parallel study, comparing the efficacy and safety of BA6101 and placebo in postmenopausal women with osteoporosis at high risk of fracture. The Phase 3 clinical trial was completed in August 2021, with 448 subjects (337 subjects in the BA6101 group and 111 subjects in the placebo group, which were randomized in a ratio of 3:1) arranged in 45 clinical study centers in China. The BA6101 group received a 60 mg injection of BA6101 every six months, and the placebo group received a 1 mL placebo injection every six months. There are two treatment cycles in total. All subjects were postmenopausal women who are diagnosed with osteoporosis at a high risk of fracture. As Prolia® had not been imported into China at that time, the CDE agreed that the reference drug of the clinical trial can use a placebo and the trial shall be designed as a superiority trial.

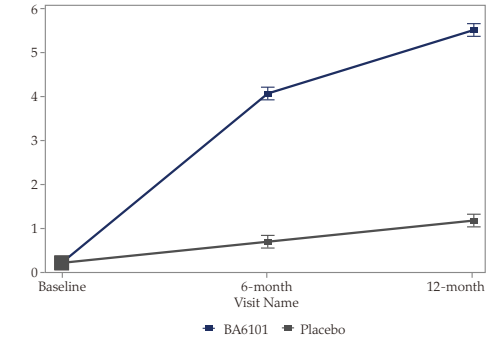


The primary endpoint was the mean percent change in lumbar spine BMD from baseline to 12 months.

Secondary endpoints included: (i) the mean percent change in lumbar spine BMD from baseline to six months; (ii) the mean percent changes in total hip, femoral neck and trochanter BMD from baseline to six and 12 months; (iii) the median percent changes in S-CTX and P1NP from baseline to one, six and 12 months.

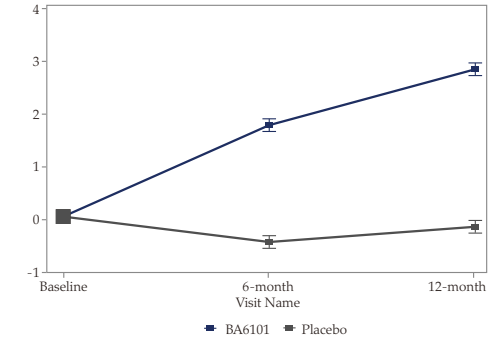
Efficacy. With respect to primary endpoint findings, based on the FAS, the least squares mean ("**LSM**") of percent change in lumbar spine BMD from baseline at 12 months in the BA6101 and placebo groups were 5.63% and 0.92%, respectively. The difference in LSM between the BA6101 group and the placebo group was 4.71%, with a 95% CI of 3.81% to 5.60% and P value < 0.0001, which is statistically significant. The following diagrams set out more detailed 12-month treatment results for the percent change from baseline in lumbar spine BMD and secondary endpoint findings:

Ratio of change from
Baseline in Lumbar spine
LSM (±SE)



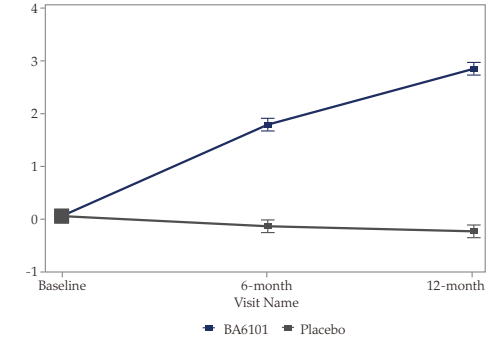
BA6101 n=320 n=320 n=309
Placebo n=107 n=107 n=98

Ratio of change from
Baseline in Total Hip BMD
LSM (±SE)



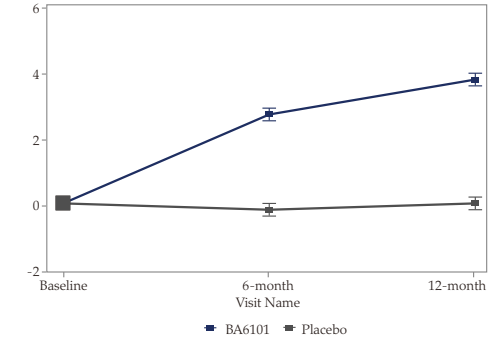
BA6101 n=320 n=319 n=309
Placebo n=107 n=107 n=98

Ratio of change from
Baseline in Femoral Neck BMD
LSM (±SE)



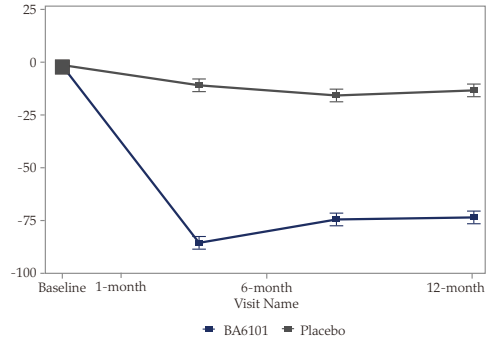
BA6101 n=320 n=319 n=309
Placebo n=107 n=107 n=98

Ratio of change from
Baseline in Trochanter BMD
LSM (±SE)



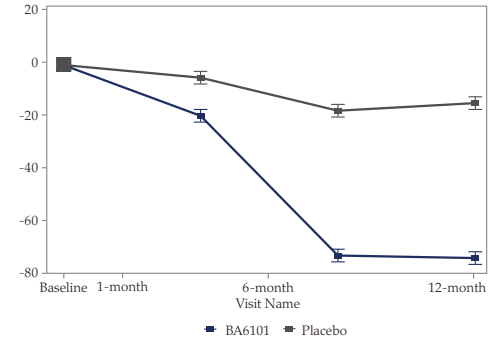
BA6101 n=320 n=319 n=309
Placebo n=107 n=107 n=98

Ratio of change from Baseline
in S-CTX
Median (Q1, Q3)



BA6101 n=320 n=311 n=310 n=308
Placebo n=107 n=102 n=101 n=98

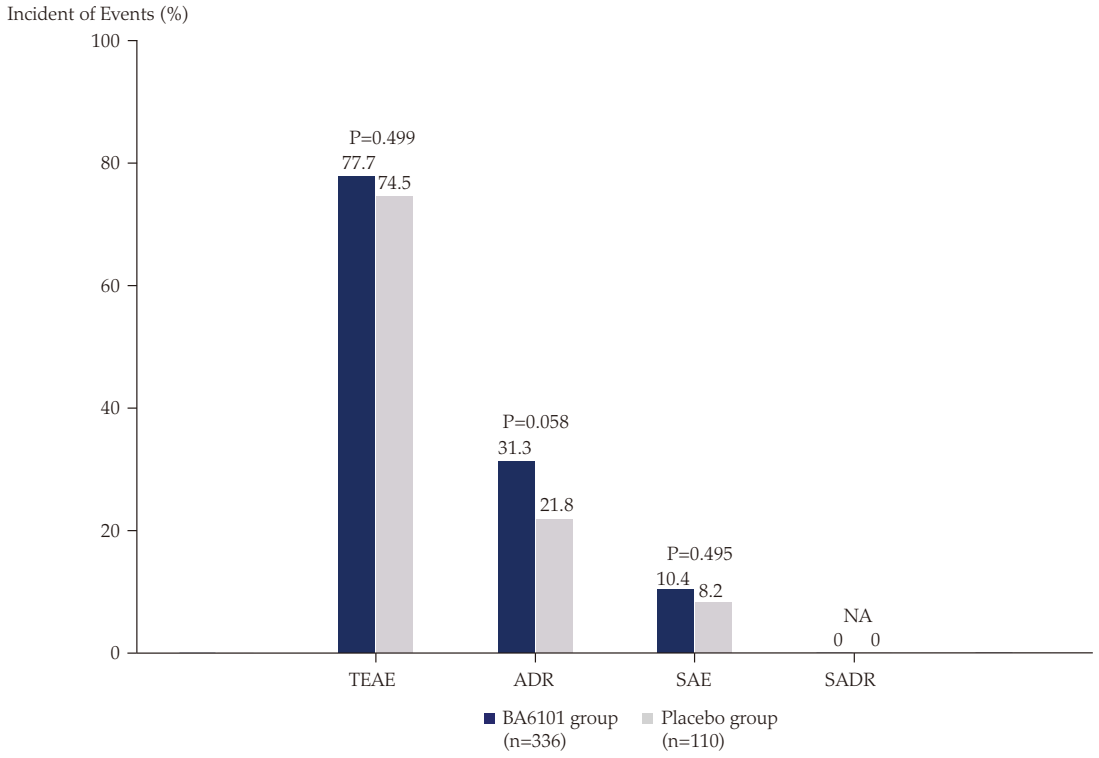
Ratio of change from Baseline
in P1NP
Median (Q1, Q3)



BA6101 n=320 n=311 n=310 n=308
Placebo n=107 n=102 n=101 n=98

There were statistically significant differences between the BA6101 group and the placebo group for secondary endpoint findings (in each case, $P < 0.0001$).

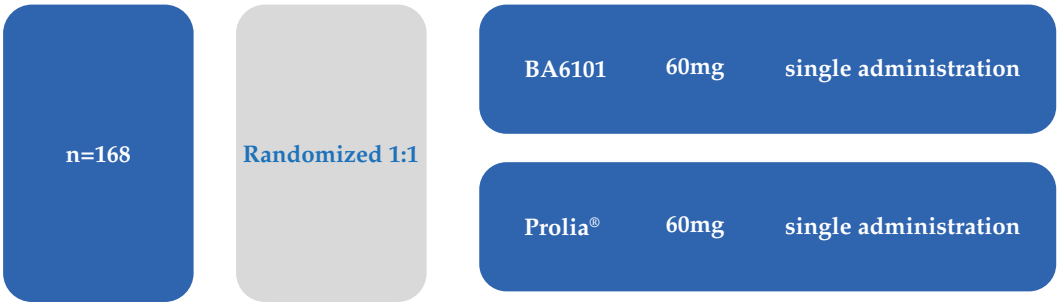
Safety. There were no statistically significant differences in the incidence rates of TEAEs, ADRs, SAEs, TEAEs or ADRs leading to discontinuation or withdrawal from the trial between the BA6101 group and the placebo group. The incidence rate of ADRs in the BA6101 group and the placebo group was 31.3% and 21.8%, respectively. The severity of adverse events during treatment was mainly mild to moderate, including decreased blood alkaline phosphatase, back pain, arthralgia and other adverse drug reactions. No TEAEs or SAEs leading to death occurred during the trial. The following diagram sets forth the safety findings in more detail:



Immunogenicity. After receiving study drug, none of the subjects in the placebo group was tested positive for ADA, and four subjects in the BA6101 group showed at least once ADA-positivity, of which one developed NAbs. ADA and NAb did not affect the efficacy and drug-time curve trend, and the BA6101 was well tolerated.

Phase 1b clinical trial in China

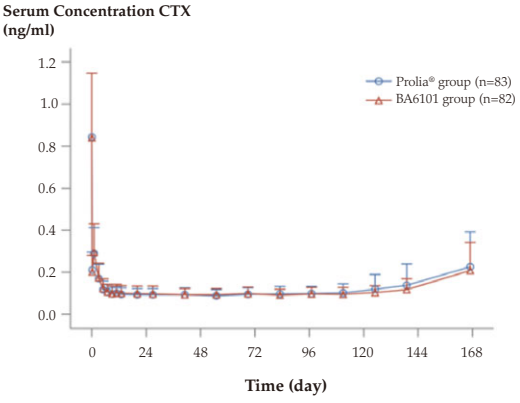
Study design. The Phase 1b clinical trial was a randomized, double-blind, parallel-controlled study, comparing the PK, PD and safety of BA6101 and Prolia® in healthy adult male subjects which is a standalone clinical trial. The Phase 1b clinical trial was completed in September 2021. 168 subjects (84 in each of the BA6101 and Prolia® group) were enrolled, and each received a single dose of 60 mg of BA6101 or Prolia®.

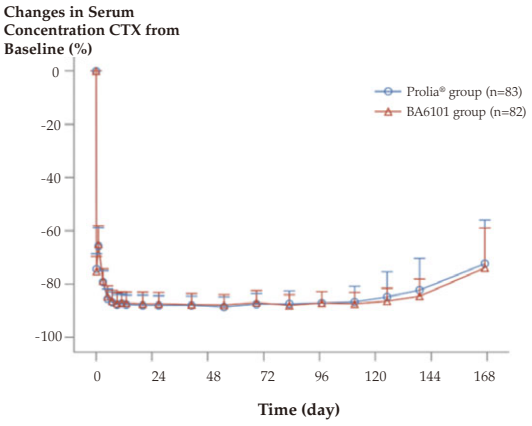


The primary endpoints were $AUC_{0-\infty}$ and C_{max}.

Secondary endpoints included observing: (i) AUC_{0-t}; (ii)T_{max}; (iii) CL/F; (iv) λ_z; (v) $t_{1/2}$; (vi) Apparent volume of distribution ("**V_z/F**"); (vii) PD parameters (the percent change in serum CTX from baseline); and (viii) the incidence of ADA-positive results and NAb-positive results.

PK/PD. After a single dose of 60 mg of BA6101 or Prolia® by subcutaneous injection, the mean pharmacodynamic-time curve trends of measured serum CTX values and the reduction in serum CTX concentrations of the two experimental groups were very similar. The geometric mean ratios of $AUEC_{0-t}$ and E_{max} and their 90% CI of both groups were within the marginal range of 80.00% to 125.00%. The following diagrams set out the findings in more detail:

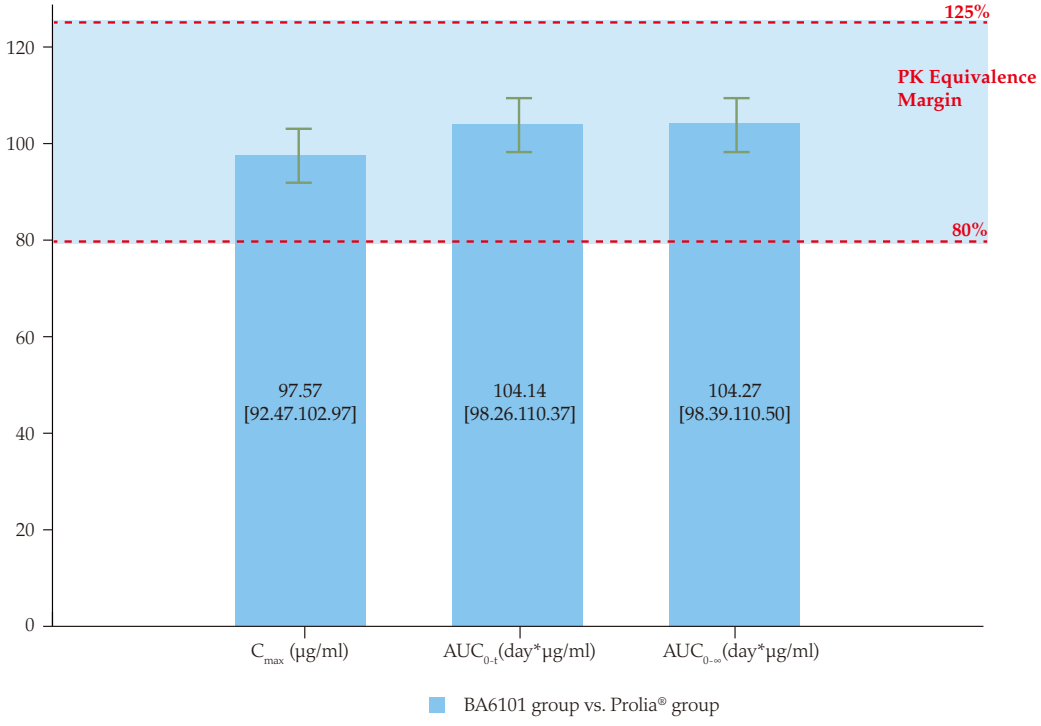




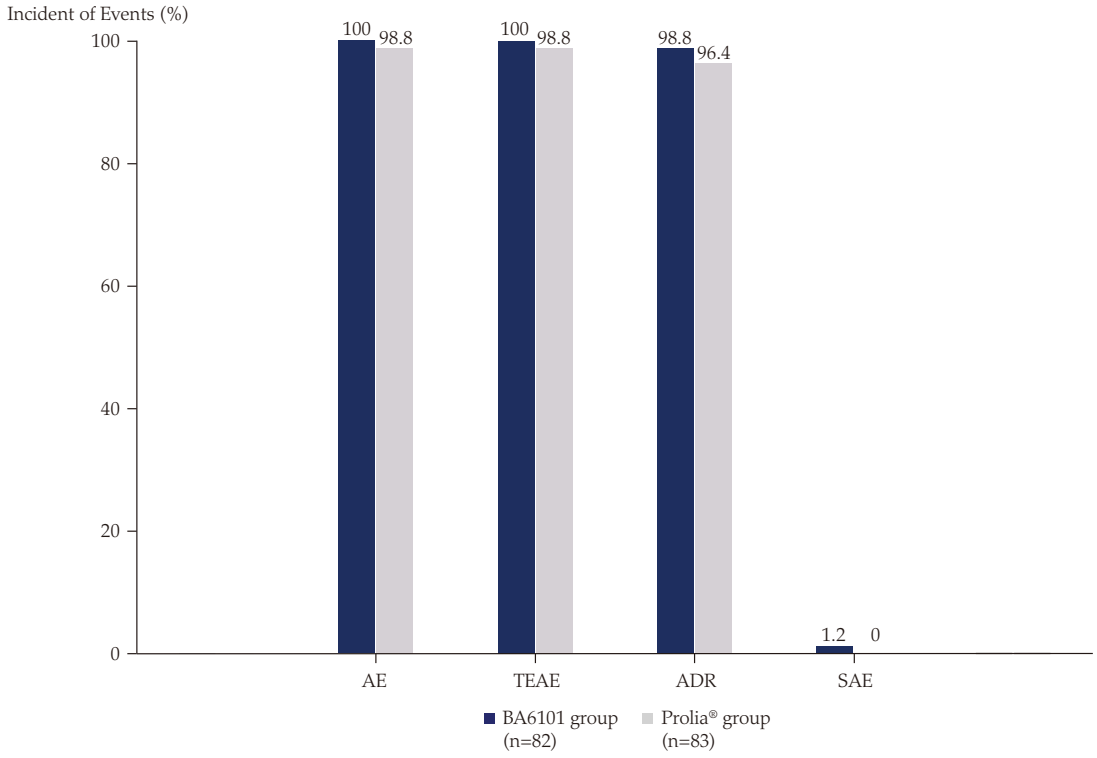
	Geometric mean		Geometric ratio	90% CI
Parameters	**BA6101**	**Prolia®**	**(BA6101/Prolia®)**	**(BA6101/Prolia®)**
$AUEC_{0-t}$ (day*%)	14178.61	14037.60	101.00%	99.00%~103.05%
E_{max} (%)	89.65	89.98	99.64%	98.71%~100.58%

The two experimental groups also established equivalent PK characteristics with respect to $AUC_{0-\infty}$ and C_{max}, i.e., as the 90% CI of the geometric mean ratio of $AUC_{0-\infty}$ and C_{max} was within the predefined 80-125% equivalence margin, namely the PK equivalence has been achieved. The following diagram sets out the findings in more detail:

C_{max} AUC_{0-t} $AUC_{0-\infty}$ Least Square Geometric Mean Ratio



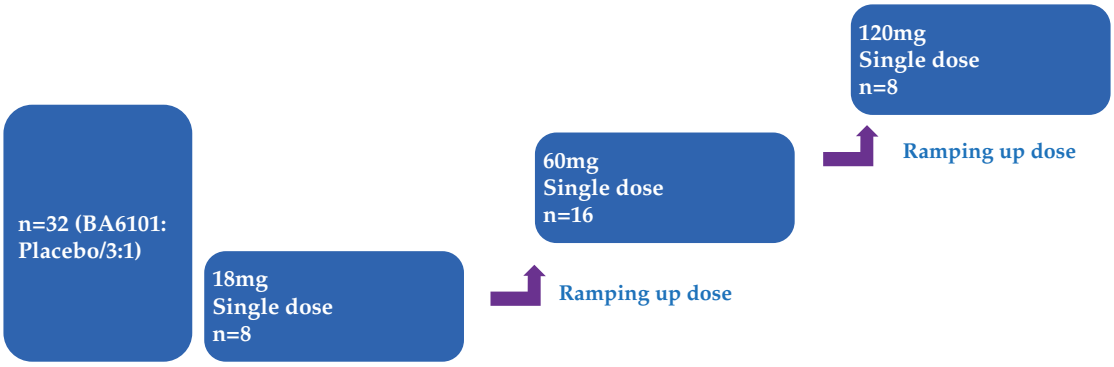
Safety. The incidence and severity of adverse events caused by BA6101 and Prolia® were similar. The incidence rate of TEAEs was 100.0% and 98.8% in the BA6101 group and Prolia® group, respectively. The incidence rate of ADRs was 98.8% and 96.4% in the BA6101 group and Prolia® group, respectively. Elevated blood parathyroid hormone was the most common ADR in both groups. The incidence of elevated blood parathyroid hormone was 82.9% and 77.1% in the BA6101 group and Prolia® group, respectively. Subjects in both groups experienced predominantly Grade 1 ADRs. In addition, during the course of the clinical trial, there were no TEAE of Grade 3 or above, no TEAE leading to death or withdrawal from the trial, and no serious adverse drug reactions, and similar immunogenicity and safety profiles were observed. The following diagram sets forth the safety findings in more detail:



Immunogenicity. The ADA test results of all subjects in the BA6101 group and the Prolia® group were negative.

Phase 1a clinical trial in China

Study design. The Phase 1a clinical trial was a randomized, double-blind, placebo-controlled study, evaluating the PK, PD and safety of BA6101 in healthy subjects. The Phase 1a clinical trial was completed in May 2019. 32 subjects (eight subjects in the 18 mg dose group with six subjects in the BA6101 group and two subjects in the placebo group; 16 subjects in the 60 mg dose group with 12 subjects in the BA6101 group and four subjects in the placebo group; and eight subjects in the 120 mg dose group with six subjects in the BA6101 group and two subjects in the placebo group) were enrolled, and each received a single dose of BA6101 or placebo.

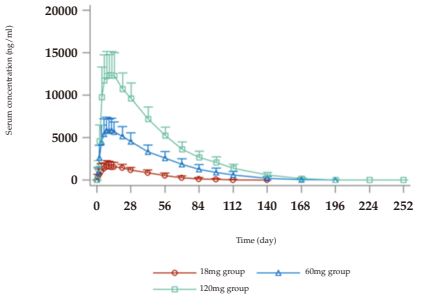


The PK endpoints included (i) C_{max}; (ii) AUC_{0-t}; (iii) $AUC_{0-\infty}$; (iv) T_{max}, (v) $t_{1/2}$; (vi) V_z/F; (vii) apparent clearance ("**CL_z/F**"); (viii) λ_z, (ix) mean residence time from 0 to t (time to detectable minimum drug concentration) ("**MRT_{0-t}**"); (x) mean residence time from 0 extrapolated to infinity ("**$MRT_{0-\infty}$**"); and (xi) percent of the extrapolated area under the curve ("**$AUC_{\_\%Extrap}$**").

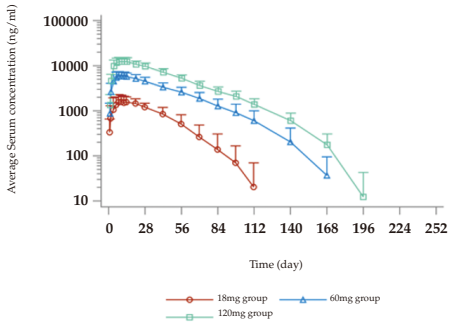
The PD endpoints included, during the follow-up period of each dose group, (i) CTX-1, (ii) bone alkaline phosphatase ("**BALP**") and P1NP from baseline to after dosing; and (iii) PD parameters such as area under the effect-time curve from time 0 to last measured time ("**AUE_{0-t}**"), E_{max}, TE_{max}, etc.

PK/PD. After a single-dose subcutaneous injection of BA6101 in healthy subjects, C_{max} was characterized by a linear PK within the dose range of 18 - 120 mg. The C_{max} and AUC were characterized by linear PK within the dose range of 60 - 120 mg. After a single-dose subcutaneous injection of 18 - 120 mg BA6101 in healthy subjects, the trends of CTX-1 concentrations in serum over time were consistent, and the duration of maintenance of CTX-1 inhibition was positively correlated with the dose administered. The trends of BALP concentrations in serum over time were consistent, all showing a slow decrease. The following diagrams set out the findings in more detail:

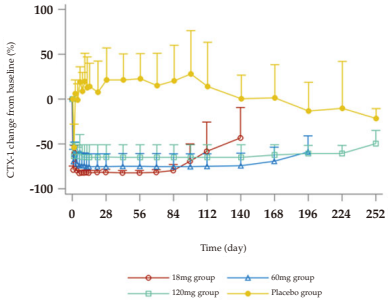
Average Serum Concentration – Time Plot of Healthy Subjects after Single Subcutaneous Injection of BA6101



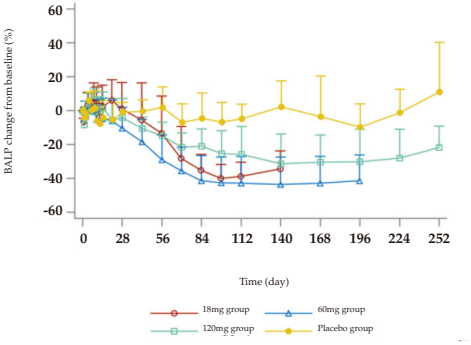
Average Serum Concentration – Time Semilog Plot of Healthy Subjects after Single Injection of BA6101



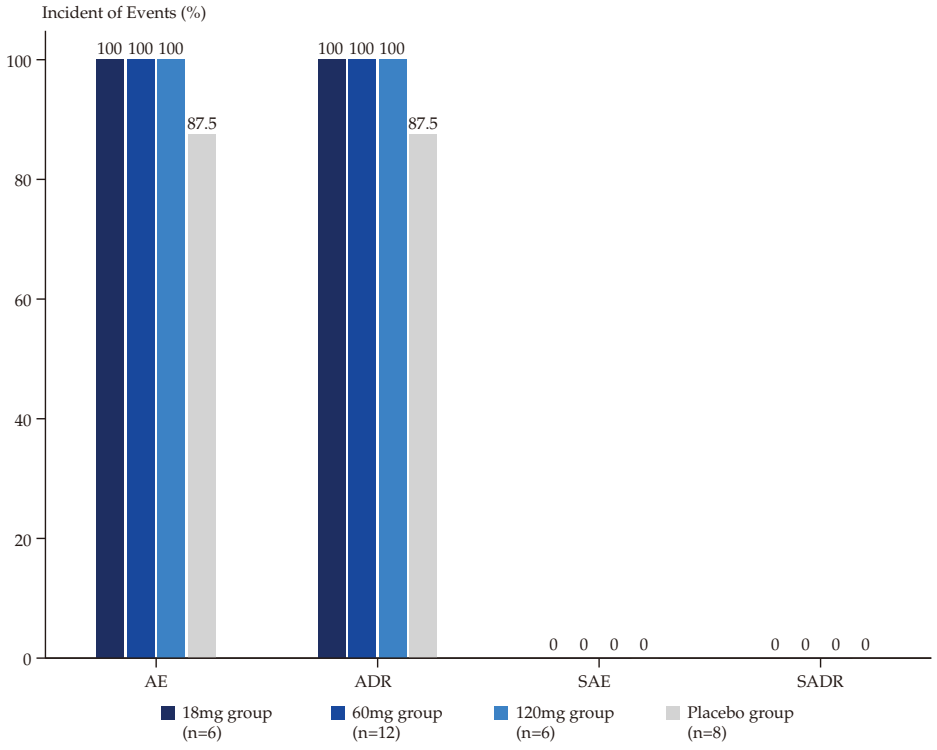
Average Efficacy – Time Plot of Healthy Subjects in Serum CTX-1 Change from Baseline after Single Subcutaneous Injection of BA6101 Injection/Placebo (PDOS)



Average Efficacy – Time Plot of Healthy Subjects in Serum BALP Change from Baseline after Single Subcutaneous Injection of BA6101 Injection/Placebo (PDOS)



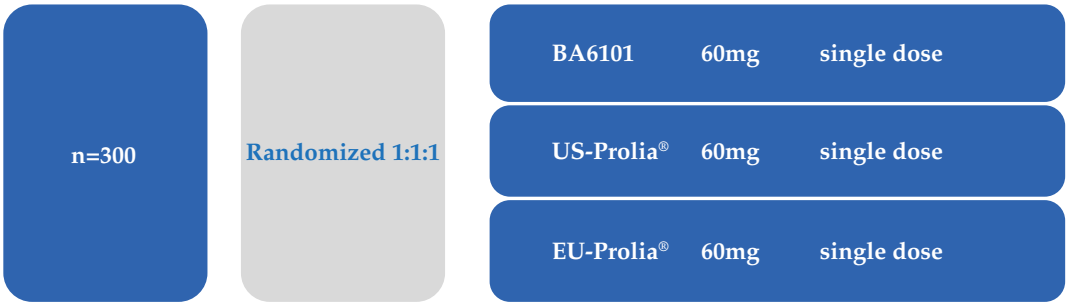
Safety. A total of 24 (100.0%) subjects in the investigational drug group experienced 204 treatment-emergent adverse reactions ("**TEARs**"), including 42 events of six (100.0%) subjects in the 18 mg dose group, and 95 events of 12 (100.0%) subjects in the 60 mg dose group, 67 events of 6 (100.0%) subjects in the 120 mg dose group, 16 events of 7 (87.5%) subjects in the placebo group. The TEARs were mostly of grade 1 or 2. Grade 3 TEARs were reported as follow: in the 18 mg dose group, 1 (16.7%) subject experienced 1 hypophosphataemia; in the 120 mg dose group, 1 (16.7%) subject experienced 1 pulpitis dental; no grade 4 TEARs occurred. There were no treatment-emergent SAE, or withdrawal from the study due to TEAEs. The following diagram sets forth the safety findings in more detail:



Immunogenicity. The ADA test results of all subjects in the BA6101 group and the placebo group were negative.

Ongoing international Phase 1 clinical trial

Study design. The ongoing international Phase 1 clinical trial is a randomized, double-blind, three-arm parallel study comparing the PK, PD and safety of BA6101, US-Prolia® and EU-Prolia® in healthy adult male subjects in Germany. As of the Latest Practicable Date, the Phase 1 clinical trial was ongoing, and approximately 300 subjects are expected to be enrolled (approximately 100 in each test group) with each to receive a single dose of 60 mg of BA6101, US-Prolia® or EU-Prolia®.



The primary endpoints were (i) AUC_{0-t}; (ii) C_{max}; and (iii) $AUC_{0-\infty}$.

The secondary endpoints included (i) T_{max}; (ii) $t_{1/2}$; (iii) CL/F; (iv) V_d; (v) λ_z; (vi) percentage of $AUC_{0-\infty}$ obtained by extrapolation ("**%AUC_{ex}**"); (vii) PD parameters (serum CTX concentration); and (viii) the incidence of ADA-positive results and NAb-positive results.

PK/PD and safety. As of the Latest Practicable Date, the international Phase 1 clinical trial was ongoing, and thus PK/PD and safety findings were not yet available.

Pre-clinical research

Compared with Prolia®, BA6101 has the same PK profile; the binding activity and inhibitory effect are similar; the toxic reactions are of the same nature and similar degree, without occurrence of any new toxic reactions, and the two drugs have similar toxicokinetic profiles. Therefore, BA6101 and Prolia® are biosimilars in terms of PD, PK, tissue cross-reactivity, and toxicokinetics.

R&D plan in the United States and the EU

According to the Frost & Sullivan Report, based on a comprehensive systemic review and meta-analysis published in 2021, the overall global prevalence of osteoporosis in the elderly women was 35.3% and in the elderly men was 12.5%. The prevalence of osteoporosis in the EU and the United States was 16.7%, and 11.5%, respectively. Global osteoporosis drug market size increased from US$13.2 billion in 2017 to US$16.8 billion in 2021, with a CAGR of 6.2%, and is expected to continue to increase to US$27.6 billion in 2030, with a CAGR of 5.7% from 2021 to 2030. The global denosumab market size of Prolia® and its biosimilars increased from US$2,164.2 million in 2017 to US$3,593.1 million in 2021, with a CAGR of 13.5%, and is expected to increase to US$3,984.7 million in 2030, with a CAGR of 1.2% from 2021 to 2030. As the United States and the EU markets contribute to a large portion of the global market, we decide to commercialize BA6101 in the United States and the EU. In addition, in the United States, the annual cost of Prolia® for 2021 was approximately US$2,868.3 per patient. In China, the annual cost of Prolia® for 2021 was approximately RMB1,247.1 per patient. Similarly, as advised by Frost & Sullivan, the pricing of biosimilars in the United States and EU are also higher than their pricing in China. Therefore, Prolia®'s pricing in the overseas market including its biosimilars' is more advantageous and entails higher profit margin, which make it easier for us to recover our upfront R&D investment.

The following table sets forth the R&D plans, regulatory framework and timeline for us to obtain market registration approvals in the United States and the EU, respectively, for BA1102 and BA6101:

BA1102/BA6101	United States	EU
R&D plans	The results of the ongoing Phase 1 clinical trial in Germany are expected to become available in the second half of 2023. We plan to initiate the Phase 3 clinical trial in the first quarter of 2023 in Germany.	
Regulatory framework	• Biologics Price Competition and Innovation Act (BPCIA)	• ICH Q5E Biotechnological/biological products subject to changes in their manufacturing process: comparability of biotechnological/biological products (CPMP/ICH/5721/03) • Guideline on similar biological medicinal products (CHMP/437/04 Rev 1)

BA1102/BA6101	United States	EU
		• Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – quality issues (EMA/CHMP/BWP/247713/2012) • Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues (EMEA/CHMP/BMWP/42832/2005 Rev 1)
The expected timeline to obtain market registration approval	2025	2025

BA6101 in the EU will be regarded as a medicinal product which is similar to a biological medicine, also known as the "reference medicine", that is already authorized in the EU. The legal basis for applications for such biosimilar medicinal products is Art. 10(4) of Directive 2001/83/EC which is implemented in the respective national legislation of each member state of the EU. BA6101 in the United States will be classified as a biosimilar product under the section 351(k) of the Public Health Service Act.

Material communications and next steps

Material communications with the NMPA/CDE

Our BA6101 has completed at least one clinical trial conducted on human subjects. The NMPA and the CDE, which are the relevant competent authorities, have no objection for us to commence the Phase 3 clinical trial to demonstrate bio-equivalency. We set forth the following key regulatory milestones in developing BA6101 including material communications with NMPA and the CDE.

IND approval

We received the IND approval from the CDE in May 2017, which permitted us to commence clinical trials, including both Phase 1 and Phase 3 clinical trials. In particular, the IND approval did not contain any condition for us to commence the Phase 1 and Phase 3 clinical trials or require us to complete or reach any main point of the Phase 1 clinical trial before commencing the Phase 3 clinical trial.

According to our PRC Legal Adviser, we have obtained all necessary approvals from the NMPA and the CDE to proceed with the BA6101's clinical trials including the Phase 1 and Phase 3 clinical trial, and the NMPA and the CDE had no objection for us to commence the Phase 3 clinical trial as planned.

Phase 1a clinical trial

We commenced the BA6101 Phase 1a clinical trial in January 2018 in China, which was completed in May 2019. The Phase 1a clinical trial was a randomized, double-blind, placebo-controlled study, evaluating the PK, PD and safety of BA6101 in healthy subjects.

Phase 3 clinical trial

On December 25, 2018, we received a written response from the CDE (the "**2018 Written Response**"), which agreed with our Phase 3 clinical trial design of BA6101 and had no objection for us to initiate the Phase 3 clinical trial. We set forth below details of the material communications with the CDE leading to the commencement of the BA6101's Phase 3 clinical trial.

On November 20, 2018, we submitted a formal meeting request to the CDE to communicate the clinical trial design of the BA6101's Phase 3 clinical trial (while we were conducting BA6101 Phase 1a clinical at that time). On December 25, 2018, we received the 2018 Written Response, which agreed with our Phase 3 clinical trial design of BA6101. As BA6101 is developed as a biosimilar, the reference product is expected to be used in the control group. However, the reference drug, Prolia®, had not been approved in China at that time. Therefore, the CDE agreed that the placebo can be used in the Phase 3 clinical trial as the control group but the study shall be designed as a superiority trial, and the target population shall be postmenopausal women with osteoporosis at high risk of fracture. In April 2019, we obtained the approval from the ethics committee of the hospital responsible for conducting BA6101's Phase 3 clinical trial. Based on the Phase 1a clinical trial result, our communications with the CDE and the approval from the ethics committee of the hospital responsible for conducting BA6101's Phase 3 clinical trial, we started the Phase 3 clinical study of BA6101 and placebo in the treatment of osteoporosis in postmenopausal women with high risk of fracture in China in June 2019.

Through our CDE drug clinical trial registration published on June 14, 2019 and our communications with the CDE as set forth above, the CDE was fully aware of BA6101's clinical trial development plan and clinical trial design of the Phase 3 clinical trial. Our PRC Legal Adviser has confirmed that there are no laws or regulations requiring any further affirmative confirmation from the CDE to approve the commencement of Phase 3 clinical trial after the 2018 Written Response from the CDE on the Phase 3 clinical trial. In addition, as confirmed by Frost & Sullivan, the above arrangements between us and the CDE are in line with the industry norm.

On July 30, 2019, we received a supplemental proposal from the CDE via email regarding our BA6101 clinical trial, which set forth additional details on the target population, design, control drug selection, sample size and primary endpoint of the Phase 3 clinical trial. On February 11, 2020, we submitted another meeting request to confirm if the Phase 3 clinical trial design of BA6101 could meet the requirements for submitting BLA. On May 12, 2020, the CDE provided written response and requested for an additional PK similarity clinical study between BA6101 and Prolia®. Based on the above communications, in December 2020, we started the PK similarity clinical study to compare the PK, PD and safety of BA6101 and Prolia® in healthy adult male subjects in China, i.e., the Phase 1b clinical trial, which was completed in September 2021.

The NMPA has accepted the BLA of BA6101 in October 2021, which can demonstrate it has no further comments on the existing clinical trial design of BA6101 to meet the requirements for submitting BLA. We received the regulatory approval to commence commercialization of BA6101 in November 2022 in China.

Other than the above, we have not had any material regulatory communications with the NMPA or CDE for BA6101, and we are not aware of any material concern from the NMPA or the CDE in connection with our BA6101.

See "— Intellectual property" for details of intellectual properties which we have registered, maintained, applied for or intend to apply for with respect to BA6101.

Material communications with the PEI, EMA and the FDA

We have requested scientific advice for BA6101 in February 2019 and received the response given by the CHMP of the EMA in April 2019 before initiating PK similarity study. In the response, the CHMP provided suggestions of developing BA1102 and BA6101, including the response to our question of whether we can obtain marketing authorization for BA1102 and BA6101 for the treatment of the indications approved for Xgeva® and Prolia®, respectively, under a single development program if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia® and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®. The CHMP responded that our overall clinical development plan is considered acceptable on the conditions that the quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia® and non-clinical similarity between BA6101 and Prolia® is established. We have obtained the CTA from the PEI, the Federal Institute for Vaccines and Biomedicines of the German Federal Ministry of Health, to initiate clinical trials in October 2020.

We submitted a follow-up scientific advice meeting request to the CHMP in January 2022 to seek advice on the acceptability of its quality updates and further comparative clinical study for the denosumab biosimilar products which are being developed in a single development program to generate biosimilars to the reference medicinal products of Prolia® and Xgeva®.

We received advice from the FDA at a Biosimilar Initial Advisory Meeting in June 2018 and a Biological Product Development (the "**BPD**") Type 2 meeting in October 2019 regarding the development plan of BA6101 and BA1102. In the BPD Type 2 meeting, the FDA agreed to our plans to develop BA6101 and BA1102 in a single global development program, including (i) a three-arm PK similarity study in healthy volunteers designed to support the demonstration of PK similarity between BA6101 and US-Prolia®, BA6101 and EU-Prolia® as well as US-Prolia® and EU-Prolia®, and (ii) a two-arm active-controlled comparative clinical study to evaluate the efficacy, safety, and immunogenicity of BA6101 compared to EU-Prolia® in postmenopausal women with osteoporosis. The initial IND was submitted in the United States on April 30, 2020 and the Study May Proceed Letter was received on June 3, 2020. A Phase 1 clinical trial is ongoing in Germany. The results are expected to become available in the second half of 2023.

Other than the above, we have not had any material regulatory communications with the PEI, the EMA or the FDA for BA6101, and we are not aware of any material concern from the PEI, the EMA or the FDA in connection with our BA6101.

Collaboration arrangements and commercialization plans

We intend to manufacture BA6101 at our Yantai Site for distribution in China. See "— Manufacturing" in this section for further details on the technologies utilized in the Yantai Site. Our marketing efforts will primarily target relevant hospitals across China. We will also explore the possibility of expanding the commercialization of BA6101 to overseas markets. We may cooperate with business partners including promoters and distributors to commercialize BA6101.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN THE COMMERCIAL SALES OF BA6101.

BA9101 aflibercept intraocular injection (a biosimilar to Eylea®)

Overview

We are developing BA9101 as an Eylea® (aflibercept) biosimilar. Eylea® (aflibercept as its generic name) is primarily used to treat patients with wAMD, DME, RVO and DR. It is a fusion protein composed of the extracellular binding domain of VEGF receptor fused with human IgG1 Fc domain. It can bind to VEGF to inhibit the binding to VEGFR, which can lead to the reduction of new blood vessels and the decrease of vascular permeability. BA9101 is administered as an ophthalmic intravitreal injection. We began developing BA9101 in January 2015. The Phase 3 clinical trial in the treatment of wAMD is ongoing in China. We expect to file the BLA to the CDE in the first half of 2024 and receive the approval in 2025.

Background of reference drug

Eylea® (aflibercept) is a soluble recombinant VEGFR ectodomain and Fc fusion protein and was developed by Bayer and Regeneron. In 2011, Eylea® was initially approved by the FDA and was subsequently approved by the EMA in 2012 for the treatment of wAMD. In 2018, Eylea® was approved by the NMPA to launch in China for treatment of wAMD and DME. Aflibercept was first added to the NRDL (2019 edition). Major patents for aflibercept will expire in the United States in 2023 and in the EU in 2025. Major patents for aflibercept in China have expired in 2020. In 2021, the global sales of Eylea® amounted to US$9.2 billion, while the sales in China amounted to RMB790.0 million according to the Frost & Sullivan Report.

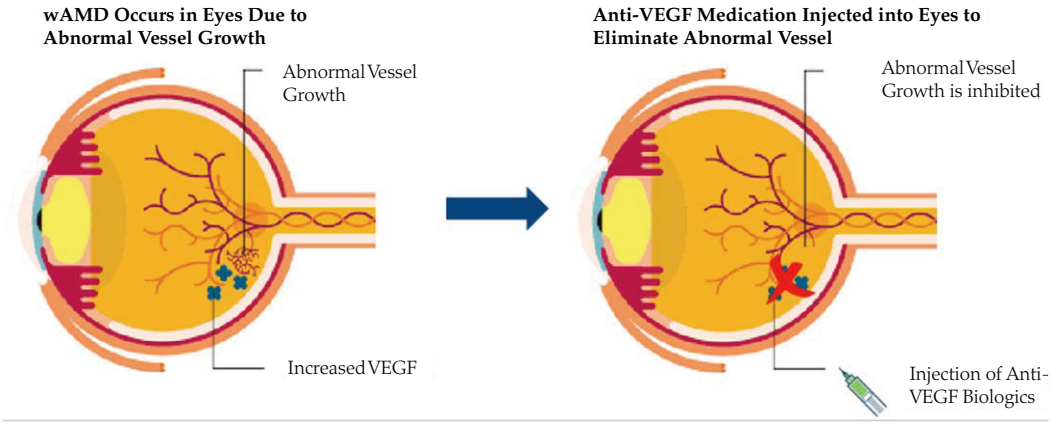
Eylea® has been approved around the world for the following indications: (i) wAMD, (ii) RVO, (iii) DME, (iv) DR, (v) myopic choroidal neovascularization and (vi) neovascular glaucoma (Japan only).

Mechanism of action

Pathological vascular growth in the retina and choroid can cause a series of clinicopathological changes, such as vitreous hemorrhage, subretinal hemorrhage, traction retinal detachment, etc., which may seriously damage the vision of the affected eye. Recent studies have shown that the pathogenesis of neovascular retinal diseases is related to the overexpression of VEGF. Therefore, VEGF is an important therapeutic target for neovascular retinal diseases, and anti-VEGF therapy has become the first-line treatment for these diseases.

Aflibercept is a fully human fusion protein, which is composed of VEGFR-1, VEGFR-2 and partial fragments of human immunoglobulin IgG1, and can more widely bind to VEGF family members. Its binding to VEGF-A and VEGF-B can block the downstream signaling pathway of VEGFR, inhibit angiogenesis and reduce vascular permeability. Aflibercept can also bind to PLGF, which synergizes with VEGF-A inhibition.

Taking wAMD as an example, abnormal blood vessels in eyes begin to grow beneath the macula and leak blood and fluid due to the increased VEGF. As a result, the central vision is gradually destroyed. By injecting anti-VEGF drugs into eyes, the formation of new blood vessels behind the retina will be inhibited and the retina is free of leakage, which leads to the recovery of the central vision. The effects usually last for a few months.



Source: Frost & Sullivan Report

Current therapies

The dosage and administration of aflibercept vary by indication such as the following examples. The treatment is mentioned in the official website for Eylea®: https://hcp.eylea.us/resources/. Anti-VEGF drugs are also mentioned as first-line treatment in preferred practice pattern guidelines published by American Academy of Ophthalmology.

wAMD: Aflibercept is widely used in wAMD. At present, anti-VEGF therapy has become the first-line therapy for wAMD recommended by guidelines of various countries. The recommended dose of aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the first 12 weeks and then once every eight weeks.

DME: As a first-line therapy for DME, the recommended dose of aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the initial five injections, followed by 2mg (0.05 mL) via intravitreal injection once every eight weeks.

RVO: As a first-line therapy for RVO, the recommended dose for aflibercept is 2 mg (0.05 mL) administered by intravitreal injection once every four weeks.

DR: As a first-line therapy for DR, the recommended dose for aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the first five injections followed by 2 mg (0.05 mL) via intravitreal injection once every eight weeks.

Potential market opportunities and competition

Retinal diseases, which are often characterized by leakage of fluid, hemorrhage and fibrous scarring in the eye, include wAMD, DME, RVO, etc. These diseases are major causes of visual impairment and blindness worldwide. Among the major types of retina diseases, the prevalences of wAMD and DME increase more rapidly than the others, which are mainly caused by risk factors such as the aging population, increasing prevalence of diabetes, etc. With the population aging and the excessive use of electronic products, the incidence of retinal diseases continues to rise. As one of the most crucial drugs for the treatment of retinal diseases in China so far, the anti-VEGF biologics market is driven by the ever-expanding number of patients. According to the Frost & Sullivan Report, the number of wAMD patients increased from 3.4 million in 2017 to 3.9 million in 2021, with a CAGR of 3.2%, and it is expected to reach 4.9 million in 2030, with a CAGR of 2.6% from 2021 to 2030. The number of DME patients increased from 6.3 million in 2017 to 7.1 million in 2021 with a CAGR of 2.9% and is forecasted to reach 8.9 million in 2030 with a CAGR of 2.5% from 2021 to 2030. The number of RVO patients increased from 7.1 million in 2017 to 7.4 million in 2021 with a CAGR of 1.2% and is forecasted to reach 7.8 million in 2030 with a CAGR of 0.6% from 2021 to 2030. Apart from the diseases mentioned above, retinopathy also has a high prevalence in patients with diabetes. In 2021, there were 134.7 million type 2 diabetic patients in China, of which about 38.2 million suffered from DR, and this number is forecasted to increase to 47.9 million by 2030 with a CAGR of 2.5% from 2021 to 2030. DR is a frequent complication of diabetes, and DME is a potential complication of DR.

Currently, anti-VEGF drugs and corticosteroids are mainly recommended for different types of retinal diseases. Before it entered the market, there was no specific therapy for wAMD patients. Approximately 70%–80% of them lost their vision within three years after being diagnosed with this disease, and almost all patients eventually become blind. According to American epidemiological studies, the rate of vision loss caused by angiogenesis was declining for the past 10 years, which is considered to be the result of using anti-VEGF biologics. After ranibizumab was approved in China in 2011, anti-VEGF biologics became a new choice for Chinese patients with retinal diseases,

which drivers market growth. According to the Frost & Sullivan Report, the global market size of anti-VEGF monoclonal antibody for retinal diseases increased from US$9.4 billion in 2017 to US$13.3 billion in 2021, with a CAGR of 9.1%, and is expected to further grow to US$28.4 billion in 2030, with a CAGR of 8.8% from 2021 to 2030. The China market size of anti-VEGF monoclonal antibody for retinal diseases increased from RMB1.4 billion in 2017 to RMB3.7 billion in 2021, with a CAGR of 28.7%, and is expected to further grow to RMB20.3 billion in 2030, with a CAGR of 20.7% from 2021 to 2030.

As of the Latest Practicable Date, there were four anti-VEGF biologics for retinal diseases approved by the FDA, being Bayer's Eylea® (aflibercept), Novartis's Lucentis® (ranibizumab), Novartis's Beovu® (brolucizumab) and Vabysmo™ (faricimab) developed by Genentech (Roche). As of the same date, in China, there were three anti-VEGF biologics for retinal diseases that had launched, being Bayer's Eylea® (aflibercept), Novartis's Lucentis® (ranibizumab) and Kanghong Pharmaceutical's Langmu® (conbercept).

Eylea® has been launched in the United States, the EU and China, the details of which are set forth below. As of the Latest Practicable Date, there was no biosimilar to aflibercept that had launched in any market.

Brand name	Company	Approval time	Indication	Annual cost per patient	2021 global sales revenue	NRDL
Eylea®	Bayer	2018-02 (China/NMPA) 2014-07 (U.S./FDA) 2014-08 (EU/EMA)	DME	~RMB36,900 (China) ~US$16,650 (U.S.) ~€6,536 (EU)	US$ 9,243.0 million	Eylea® is included in Category B(1)
		2018-05 (China/NMPA) 2011-11 (U.S./FDA) 2012-11 (EU/EMA)	wAMD	~RMB32,800 (China) ~US$14,800 (U.S.) ~€5,810 (EU)		
		2019-05 (U.S./FDA)	DR	~US$16,650 (U.S.)		–
		2014-10 (U.S./FDA) 2015-01 (EU)	RVO	~US$24,050 (U.S.) ~€9,441 (EU)		–
		2015-09 (EU)	mCNV	~€8,715 (EU)		–

Note:

(1) Drugs included in the NRDL Category B typically have reimbursement percentages ranging between 70%-90% with variations among provinces.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were nine clinical-stage aflibercept biosimilars globally (outside China), further details of which are set forth below:

Region	Drug name/code	Company	Indication	Phase	First posted date
Global	MYL-1701P	Mylan Pharmaceuticals	DME	Phase 3	2018-08-01
Slovakia	CT-P42	Celltrion	DME	Phase 3	2021-02-04
Global	ABP-938	Amgen	wAMD	Phase 3	2020-02-17
Global	SB15	Samsung Bioepis	wAMD	Phase 3	2020-06-29
Global	SCD411	Sam Chun Dang Pharm	wAMD	Phase 3	2020-07-21
Global	FYB203	Bioeq GmbH	wAMD	Phase 3	2020-08-21
Global	SOK583A1	Sandoz	wAMD	Phase 3	2021-04-29
NA	AVT06	Alvotech Swiss AG	wAMD	Phase 3	2021-12-13
Korea	ALT-L9	Alteogen	wAMD	Phase 1	2019-08-15

Notes:

(1) NA means region of clinical trial is not publicly available.

(2) Global means clinical trials are carried out in multiple regions of the world.

(3) For overseas biosimilars to enter the China market, data from overseas clinical trials can be accepted for BLA since "The Technical Guidelines for Acceptance of Clinical Trial Data from Overseas for Pharmaceuticals" was released in 2018.

Source: Frost & Sullivan Report

As of the Latest Practicable Date, there were four clinical-stage aflibercept biosimilars in China, further details of which are set forth below:

Region	Drug name/code	Company	Indication	Phase	First posted date
China/NMPA	**BA9101**	**Our Group**	**wAMD**	**Phase 3**	**2020-11-03**
	QL1207	Qilu Pharma	wAMD	BLA	2022-04-28
			DME	Phase 1	2018-12-07
	9MW0813	Jiangsu T-mab BioPharma | Mabwell | Shanghai Destiny Biotech	DME	Phase 3	2021-10-18
	JZB05	Jingze Pharma	DME	Phase 1	2022-06-21

Source: Frost & Sullivan Report

Eylea® is a fully human fusion protein. In 2021, the global sales of Eylea® amounted to US$9.2 billion, which was the highest among the approved anti-VEGF monoclonal antibodies for retinal diseases globally. In China, the sales revenue of Eylea® amounted to RMB790.0 million in 2021. After Eylea® was launched in overseas market, it quickly became one of the world's best-selling drugs. Eylea® has been proved to have an advantage in the treatment of DME comparing with macular laser photocoagulation treatment method. Experiment supported its efficacy by a positive outcome from the Phase 3 VISTA-DME clinical trials. The mean changes in best-corrected visual acuity were significantly improved compared with the control group after one year.

As of the Latest Practicable Date, there was only one competitor, Qilu Pharma's AL1207, which submitted the BLA. BA9101 was under Phase 3 clinical trial and potentially will be the second biosimilar to Eylea® (aflibercept) to be launched in China. BA9101 is potentially one of the first-to-market biosimilar drugs in China targeting wAMD and DME and we aim to become the first- or early-mover to occupy market share ahead of other competitors in China, which generally is less susceptible to price competition from competitors falling behind on their product launch. In addition, as a leading enterprise in terms of ophthalmic drugs, OcuMension is specialized in accelerating the penetration in the China ophthalmology market. As of December 31, 2021, OcuMension had achieved a coverage of 1,024 hospitals nationwide according to its annual report of 2021. Based on the above, we believe BA9101 will be well positioned to compete in the market and gain a leading market share following its launch.

Summary of clinical development history and results

As of the Latest Practicable Date, a multi-center Phase 3 clinical trial was ongoing in China for BA9101. We have completed Phase 1 clinical trial in China. Based on the data collected and analyzed in the Phase 1 clinical trial, we concluded that a single intravitreal injection of BA9101 or Eylea® in subjects with wAMD had similar average drug-time curves of the combined drug and the free drug and the PK results were consistent with each other. There was an initial improvement in visual acuity and central retinal thickness in subjects of both groups. Overall safety and tolerability were good. All subjects were negative for ADA.

We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, pursuant to which we are responsible for conducting certain initial stages of the Phase 3 clinical trial and commercial production as well as submitting the BLA of BA9101 and OcuMension is responsible for completing the rest of Phase 3 clinical trial and promoting and commercializing BA9101 in China. For more details, see "— Commercialization, sales, marketing and distribution — R&D partner and promoter" in this section.

Clinical development

The chart below summarizes the development timeline of BA9101:

Ongoing Phase 3 clinical trial

Study design. The ongoing Phase 3 clinical trial is a multicenter, randomized, double-blind, parallel, active drug-controlled study, comparing the efficacy and safety of BA9101 and Eylea® in the treatment of patients with wAMD. The clinical trial involved about 416 subjects that are divided into two groups in a 1:1 ratio. The clinical trial is involving approximately 25 clinical research centers in China. The subjects in the two groups were administered a total of eight times and the dose of each group was 2 mg. The trial will continue for 52 weeks.

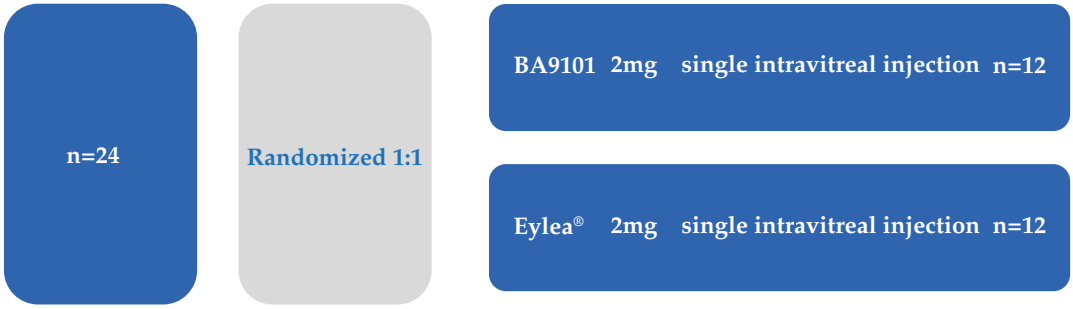
The primary endpoint was the eye's best corrected visual acuity ("**BCVA**") at 24 weeks compared with the baseline by using the early treatment diabetic retinopathy study ("**ETDRS**") chart.

Secondary endpoints included: (i) change from baseline in the study eye's BCVA at each visit by using ETDRS vision chart; (ii) the proportion of subjects' eyes with an increase of ≥5, 10, or 15 letters from baseline at weeks 24 and 52; (iii) change from baseline in central retinal thickness of the study eye's at weeks 24 and 52; and (iv) change in the leakage area of choroidal neovascularization ("**CNV**") in the study eye relative to the baseline at week 24 and 52.

Efficacy and safety. As of the Latest Practicable Date, the Phase 3 clinical trial in China for the treatment of wAMD was ongoing, and thus efficacy and safety results were not yet available.

Phase 1 clinical trial

Study design. The Phase 1 clinical trial was a multi-center, randomized, double-blind, parallel-controlled, single-dose study to compare the safety, tolerability, PK and immunogenicity characteristics of BA9101 with Eylea® in patients with wAMD and to conduct a preliminary evaluation of the efficacy of a single intravitreal injection of BA9101 in the treatment of patients with wAMD. The Phase 1 clinical trial, which was completed in October 2020, enrolled 24 subjects (12 subjects in each study group) who received a single intravitreal injection of 2 mg of BA9101 or Eylea®. The trial duration was approximately 43 days.



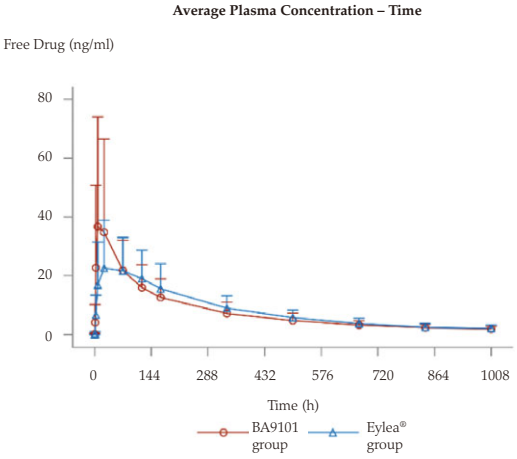
Safety endpoints were (i) AE; (ii) vital signs; (iii) physical examination; (iv) laboratory tests; (v) 12-lead ECG; and (vi) intraocular pressure and standard ophthalmic examinations (slit lamp and fundus examination).

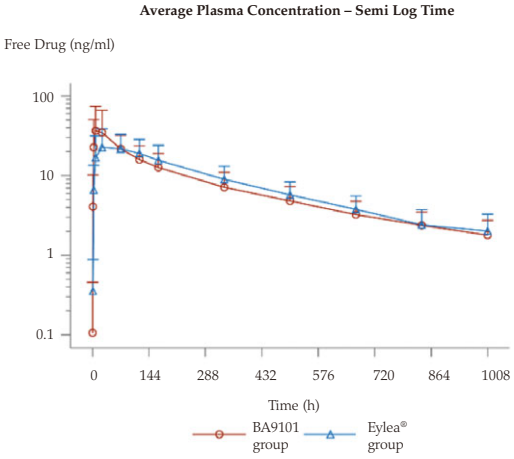
Pharmacokinetic endpoints included (i) AUC_{0-t}; (ii) $AUC_{0-\infty}$; (iii) C_{max}; (iv) T_{max}; (v) $t_{1/2}$; and (vi) CL/F.

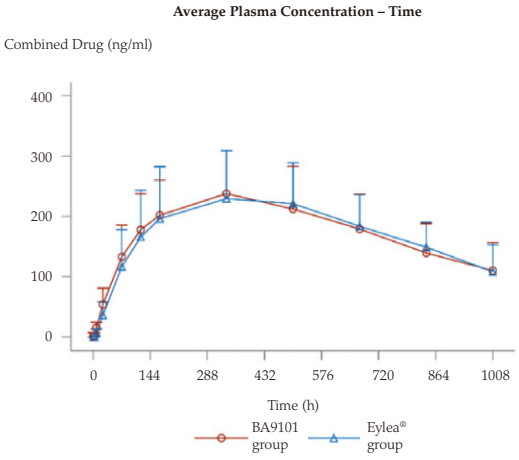
Efficacy endpoints included (i) change from baseline in central retinal thickness on days 29 and 43; and (ii) BCVA change from baseline on days 29 and 43 by using the ETDRS vision chart.

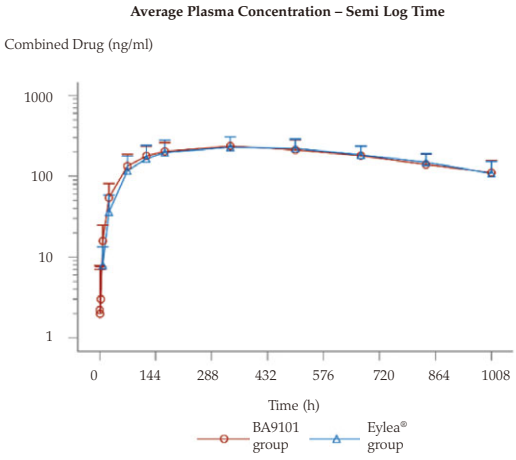
Immunogenicity was assessed based on the incidence of ADA-positive results and NAb-positive results.

PK. With a single intravitreal injection of 2 mg of BA9101 or Eylea®, the average drug-time profiles of the combined drug and the free drug were similar in both groups and the PK results were consistent. The following diagrams set out the findings in more detail:



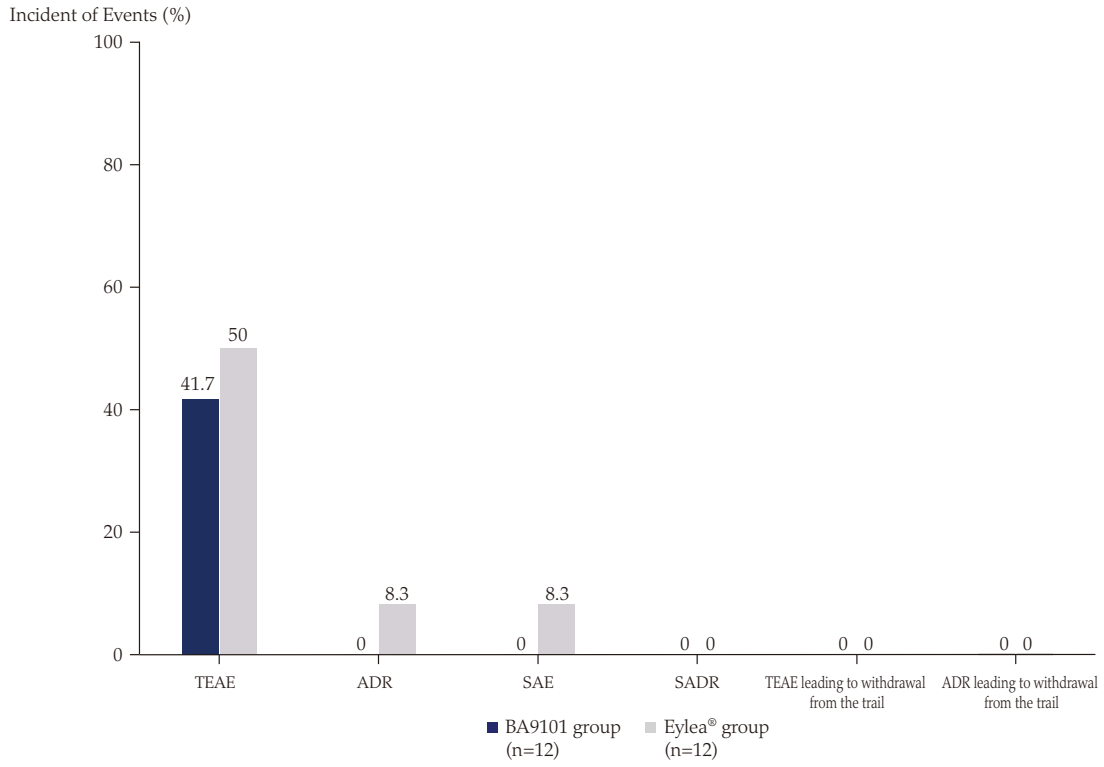






Efficacy. A single intravitreal injection of 2 mg of BA9101 or Eylea® resulted in an increase in the improvement in the number of letters in the study eye from the baseline in both test groups and also a consistent decrease in the central retinal thickness in the study eye.

Safety. The incidence and severity of adverse events caused by BA9101 and Eylea® were similar. The incidence rate of TEAEs during treatment in the BA9101 and Eylea® groups was 41.7% and 50.0%, respectively. TEAEs experienced by subjects in both groups were mild. Only one ADR occurred in the Eylea® group during the study period, characterized by conjunctival hemorrhage of the study eye. During the study, only one subject in the Eylea® group experienced one SAE unrelated to the study drug. There was no post-treatment death or adverse event leading to withdrawal from the trial. The following diagram sets forth the safety findings in more detail:



Immunogenicity. The ADA test results of all subjects in the BA9101 group and the Eylea® group were negative.

Pre-clinical research

We evaluated BA9101 drug substance and injection in terms of physicochemical properties, biological activity, purity and impurities, and immunological characteristics and performed a comprehensive comparison with Eylea®. The results of the quality comparison study showed that BA9101 was highly similar to Eylea® in terms of protein structure, biological activity, purity and impurities.

According to the results of quality comparison study, a comparative study of pharmacodynamics, pharmacokinetics and repeated-dose toxicity tests was carried out in non-clinical studies. The results of pharmacokinetic and toxicokinetic studies showed that the intravitreal free drug exposure of BA9101 eyes was similar to that of Eylea®, and the bound drug exposure was essentially similar to Eylea®; there were some differences in the free and bound drug exposures in plasma. Molecular pharmacology, pharmacodynamics, immunogenicity and toxicity comparison studies have all shown biosimilarity and can be used to support clinical trial application.

R&D plan in the United States and the EU

According to the Frost & Sullivan Report, the global market size of anti-VEGF monoclonal antibody for retinal diseases increased from US$9.4 billion in 2017 to US$13.3 billion in 2021, with a CAGR of 9.1%, and is expected to further grow to US$28.4 billion in 2030, with a CAGR of 8.8% from 2021 to 2030. As the United States and the EU markets contribute to a large portion of the global market, we decide to commercialize BA9101 in the United States and the EU. In addition, in the United States, the annual cost of Eylea® for 2021 was from approximately US$14,800 to approximately US$24,050 per patient, depending on the different indications. In the EU, the annual cost of Eylea® for 2021 was from approximately €5,810 to approximately €9,441 per patient, depending on the different indications. In China, the annual cost of Eylea® for 2021 was from approximately RMB32,800 to approximately RMB36,900 per patient, depending on the different indications. Similarly, as advised by Frost & Sullivan, the pricing of biosimilars in the United States and EU are also higher than their pricing in China. Therefore, Eylea®'s pricing in the United States and the EU including its biosimilars' is more advantageous and entails higher profit margin, which make it easier for us to recover our upfront R&D investment.

The following table sets forth the R&D plans, regulatory framework and timeline for us to obtain market registration approvals in the United States and the EU, respectively, for BA9101:

BA9101	United States	EU
R&D plans	We will communicate the overseas clinical trials with the FDA after the completion of Phase 3 clinical trial in China. We plan to complete the Phase 3 clinical trial in China in the fourth quarter of 2023.	We will communicate the overseas clinical trials with the EMA after the completion of Phase 3 clinical trial in China. We plan to complete the Phase 3 clinical trial in China in the fourth quarter of 2023.
Regulatory framework	Biologics Price Competition and Innovation Act (BPCIA)	• ICH Q5E Biotechnological/biological products subject to changes in their manufacturing process: comparability of biotechnological/biological products (CPMP/ICH/5721/03) • Guideline on similar biological medicinal products (CHMP/437/04 Rev 1) • Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – quality issues (EMA/CHMP/BWP/247713/2012) • Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues (EMEA/CHMP/BMWP/42832/2005 Rev 1)
The expected timeline to obtain market registration approval	We will formulate the timetable after the communication with the FDA.	We will formulate the timetable after the communication with the EMA.

Material communications and next steps

We received the IND approval from the CDE in March 2019. According to our PRC Legal Adviser, we have obtained all necessary approvals from the NMPA and the CDE to proceed with the BA9101 Phase 3 clinical trial and the NMPA and the CDE had no objection for us to commence a Phase 3 clinical trial as planned.

The Phase 3 clinical trial for wAMD is ongoing in China. We expect to file the BLA to the CDE in the first half of 2024 and receive the approval in 2025.

In preparation for the clinical trial of BA9101, we had two rounds of communications with the CDE. In the pre-IND meeting held on October 9, 2018, the design of both Phase 1 and Phase 3 clinical trial were fully discussed and agreed between the CDE and us. On January 23, 2020, we submitted a formal meeting request to confirm the Phase 3 clinical trial design in detail. On June 4, 2020, the CDE provided a written response to advise the setting of equivalence cut-off value and re-recognized the Phase 3 clinical trial design. Based on these communications with the CDE, we finalized the Phase 3 clinical trial design, which has been accepted by the CDE.

Other than the above, we have not had any material regulatory communications with the NMPA or CDE for BA9101, and we are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA9101.

We will file the BLA for the indications of wAMD and DME. According to the Technical Guidelines for Research, Development and Evaluation of Biosimilars (《生物類似藥研發與評價技術指導原則》) and Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》, on the basis of the biosimilarity established between the proposed product and reference product through totality-of-the-evidence approach, if the clinical similarity is confirmed in at least an appropriate indication, the applicant may seek licensure of the proposed product for one or more additional indications for which the reference product is licensed. At present, the reference drug of BA9101, i.e., Eylea®, was approved in China for the treatment of wAMD and DME. If the results of the clinical trial of BA9101 demonstrate the biosimilarity in the condition of wAMD, we expect to extrapolate the indication of BA9101 to DME without the need for a completed clinical trial for DME.

See "— Intellectual property" for details of intellectual properties which we have registered, maintained, applied for or intend to apply for with respect to BA9101.

Collaboration arrangements and commercialization plans

We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, under which OcuMension agreed to conduct the remaining Phase 3 clinical trial of BA9101. We have conducted certain initial parts of the Phase 3 clinical trial from February 2021 to May 2021, including selecting and deciding the research centers, passing the ethics committees and enrollment of some patients. OcuMension agrees to complete all remaining tasks relating to the Phase 3 clinical trial of BA9101, including patient enrollment, treatment and visit of patients and completing clinical study report, and has so far completed most of the work for site initiation and recruitment of the majority of patients needed for the Phase 3 clinical trial. We will be responsible for the procurement of the control drug, Eylea®, at OcuMension's expenses for the Phase 3 clinical trial.

In addition, we also granted OcuMension the exclusive right to promote and commercialize BA9101 in China in October 2020. For more details, see "— Commercialization, sales, marketing and distribution — R&D partner and promoter" in this section. We will also explore the possibility of expanding the commercialization of BA9101 to overseas markets, such as the EU and the United States, by cooperation with business partners including promoters and distributors.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA9101.

BA1104 (a biosimilar to Opdivo®)

Overview

We are developing BA1104 as an Opdivo® (nivolumab) biosimilar. Opdivo® (nivolumab as its generic name) is primarily used to treat patients with melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. We plan to commercialize BA1104 as an affordable alternative to Opdivo® primarily in China. We have completed preliminary pharmaceutical and non-clinical studies and the results have proved that BA1104 and Opdivo® are similar in pharmacy, pharmacology, pharmacodynamics, pharmacokinetics and toxicology. In February 2021, we submitted to the CDE the IND application for BA1104, becoming one of the first domestic companies to submit the IND application for nivolumab biosimilars. We obtained the IND approval from the CDE in April 2021 and initiated the Phase 1 clinical trial in China in September 2022. We plan to initiate the Phase 3 clinical trial in China in 2024.

Background of reference drug

Opdivo® was developed by Bristol-Myers Squibb. In December 2014, Opdivo® was first launched in the United States, and it was subsequently launched in more than 65 other countries or regions around the world. In June 2018, Opdivo® was approved by the NMPA to launch in China. Nivolumab had not been added to the NRDL as of the Latest Practicable Date. Major patents for nivolumab will expire in December 2028, June 2030, and May 2026 in the United States, the EU and China, respectively. In 2021, the global sales of Opdivo® amounted to US$8.5 billion, while the sales in China amounted to RMB850.7 million according to the Frost & Sullivan Report.

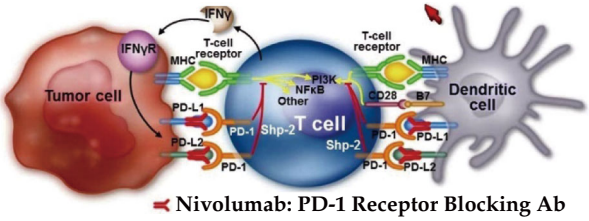
Opdivo® has been approved around the world for various indications including melanoma, NSCLC, malignant pleural mesothelioma, RCC, cHL, SCCHN, urothelial carcinoma, colorectal cancer, HCC, esophageal cancer, gastric cancer, gastroesophageal junction cancer, esophageal adenocarcinoma, etc.

Mechanism of action

Nivolumab is a human immunoglobulin G4 ("**IgG4**") monoclonal antibody ("**HuMAb**") that binds to the PD-1 receptor and blocks its interaction with PD-1 ligand 1 ("**PD-L1**") and PD-1 ligand 2 ("**PD-L2**"). The PD-1 receptor is a negative regulator of T cell activity and has been shown to be involved in the control of T cell immune responses. PD-1 binds to the ligands PD-L1 and PD-L2 expressed in antigen-presenting cells and inhibits T cell proliferation and cytokine secretion. PD-L1 and PD-L2 may also be expressed by tumors or other cells in the tumor microenvironment. Nivolumab enhances the antitumor response of T cells by blocking the binding of PD-1 to PD-L1 and PD-L2 ligands, and so it is currently the most broad-spectrum tumor therapy drug. The specific mechanism of action is shown in the diagram below.

Nivolumab Mechanism of Action

- PD-1 expression on tumor-infiltrating lymphocytes is associated with decreased cytokine production and effector function[10]
- Nivolumab binds PD-1 receptors on T cells and disrupts negative signaling triggered by PD-L1/PD-L2 to restore T-cell antitumor function[11-13]



Source: the poster published on American Society of Clinical Oncology (ASCO) in 2015

Current therapies

Nivolumab has the market potential due to a wide range of possible indications. We set forth the following examples for the therapies in using nivolumab.

NSCLC: Nivolumab is a second-line therapy for metastatic NSCLC with no EGFR or ALK genomic tumor aberrations and progression on or after platinum-based chemotherapy.

Malignant pleural mesothelioma: Nivolumab is a first-line therapy for unresectable malignant pleural mesothelioma in combination with ipilimumab.

Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma: Nivolumab is a first-line therapy for advanced or metastatic patients in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Potential market opportunities and competition

A number of PD-1 or PD-L1 antibody drugs have been approved by the FDA. These include Merck's Keytruda® (pembrolizumab), Bristol-Myers Squibb's Opdivo® (nivolumab), Regeneron/Sanofi's Libtayo® (cemiplimab), GSK's Jemperli® (dostarlimab), Roche's Tecentriq® (atezolizumab), AstraZeneca's Imfinzi® (durvalumab) and Pfizer and Merck Serono's Bavencio® (avelumab). According to the Frost & Sullivan Report, the global PD-1/L1-based antibody market size increased from US$10.1 billion in 2017 to US$34.4 billion in 2021, with a CAGR of 35.9%, and is expected to increase to US$59.4 billion in 2030, with a CAGR of 6.2% from 2021 to 2030.

We believe there is a large commercial opportunity in China for PD-1 or PD-L1 antibody drugs based on the following findings according to the Frost & Sullivan Report. In 2021, 41.6%, 44.6% and 44.7% of the worldwide mortalities from lung, gastric and liver cancers, respectively, occurred in China. Collectively, these three tumor types comprised over 1.5 million new cases in 2021 in China alone. The China PD-1/L1-based antibody market size increased from nil in 2017 to RMB14.9 billion in 2021, and is expected to increase to RMB59.9 billion in 2030, with a CAGR of 16.7% from 2021 to 2030.

As of the Latest Practicable Date, in China, there were 10 PD-1 monoclonal antibodies approved by NMPA, eight of which were domestic products. Opdivo® was the first PD-1/L1 monoclonal antibody approved for the treatment of gastric cancer in China. In China, there were two product candidates of nivolumab in clinical trial, CMAB819 developed by Mabpharm and BA1104 developed by our Group. For more details, see "Industry Overview — Oncology biologics market — Oncology biosimilars market — Nivolumab market — Competitive landscape".

BA1104 is the first biosimilar to Opdivo® approved for clinical trials according to the classification 3.3 of biological product of the Notice of NMPA on Issuing the Registration Classification of Biological Products and Requirements for Application Materials (2020 No. 43) (國家藥監局關於發佈生物製品註冊分類及申報資料要求的通告(2020年第43號)) in China. We believe BA1104 will be well positioned to compete in the market and gain a leading market share following its launch.

Summary of clinical development history and results

Clinical development

Pre-clinical research

The pharmaceutical comparability study is based primarily on a comparison of data generated from the analysis of three lots of BA1104 drug product to the data generated from the analysis of 10 lots of CHN-Opdivo® (China sourced Opdivo®) and four lots of EU-Opdivo® (EU sourced Opdivo®).

Physicochemical properties and functional activities comparability assessment were fully characterized to demonstrate the similarity between BA1104 and Opdivo®. The study contents were as follows: primary structure, charge variants, glycosylation, high order structure, biological activity (antigen-antibody binding activity, competitive binding activity, and cellular activity), sub-visible particles and general properties. The comparability of the stability at long-term and accelerated conditions, and comparability of the forced degradation profiles were also evaluated. The above studies proved the pharmaceutical similarity between the BA1104 and Opdivo®.

Pre-clinical comparability: BA1104 and Opdivo® have similar affinity binding to target antigens and binding to representative isoforms of the relevant Fcγ receptors (including FcγRIa, FcγRIIa167H, FcγRIIa167R, FcγRIIb/c, FcγRIIIa176F, FcγRIIIa176V, FcγRIIIb), FcRn and complement ("***C1q***"); BA1104 and Opdivo® have similar antitumor effects, pharmacokinetics, toxicokinetics and pharmacology profiles *in vivo*. After single IV injection of 1 mg/kg and 10 mg/kg of BA1104, systemic exposure of BA1104 increased dose-proportionally. C_{max} and AUC values were similar for BA1104 and Opdivo® at the same dose (10 mg/kg). No significant difference in other PK parameters was observed.

Material communications and next steps

We submitted the IND application of BA1104 in February 2021 and obtained the IND approval from the CDE for BA1104 in April 2021. We had regulatory communications with the CDE and received the advice about clinical trial designs from the CDE. We are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA1104.

In the EU, we plan to request a scientific advice from the CHMP on the overall clinical development plan in compliance with the EU regulation in the future.

Collaboration arrangements and commercialization plans

We intend to manufacture BA1104, once approved, at our Yantai Site for distribution in China. See "— Manufacturing" in this section for further details on the technologies utilized in the Yantai Site. Our marketing efforts will primarily target relevant hospitals across China leveraging our existing distribution network of Boyounuo® (BA1101). We will also explore the possibility of expanding the commercialization of BA1104 to overseas markets.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA1104.

BA5101 (a biosimilar to Trulicity®)

Overview

We are developing BA5101 as a Trulicity® (dulaglutide as its generic name) biosimilar. Dulaglutide is primarily used to treat patients with type 2 diabetes. We are actively promoting the research and development process of BA5101 and have completed the pre-clinical research. The results prove that BA5101 and Trulicity® have biosimilarity in pharmacy, pharmacology, pharmacodynamics, pharmacokinetics and toxicology. We obtained the IND approval in September 2021. As of the Latest Practicable Date, we were conducting the BA5101's Phase 3 clinical trial in China. We also plan to commercialize BA5101 in other countries and regions around the world when opportunities arise.

Background of reference drug

Trulicity® is a long-acting glucagon-like peptide-1 ("**GLP-1**") receptor agonist developed by Eli Lilly in the United States. It can activate GLP-1 receptor and increase the intracellular cyclic adenosine monophosphate ("**cAMP**") in beta cells leading to glucose-dependent insulin release. It also decreases glucagon secretion and delays gastric emptying. Compared with other original glucose-reducing drugs, its advantages are that it can improve pancreatic islet beta cells function, effectively reduce glycemia and HbA1c levels, and rarely cause hypoglycemia. It can also reduce weight and reduce major cardiovascular events. A number of relevant clinical studies have shown that it is a safe and effective long-acting drug for type 2 diabetes medication. Its once-a-week dosing regimen can reduce the inconvenience of patients when taking the drug, improve compliance, and improve the quality of life of patients with type 2 diabetes.

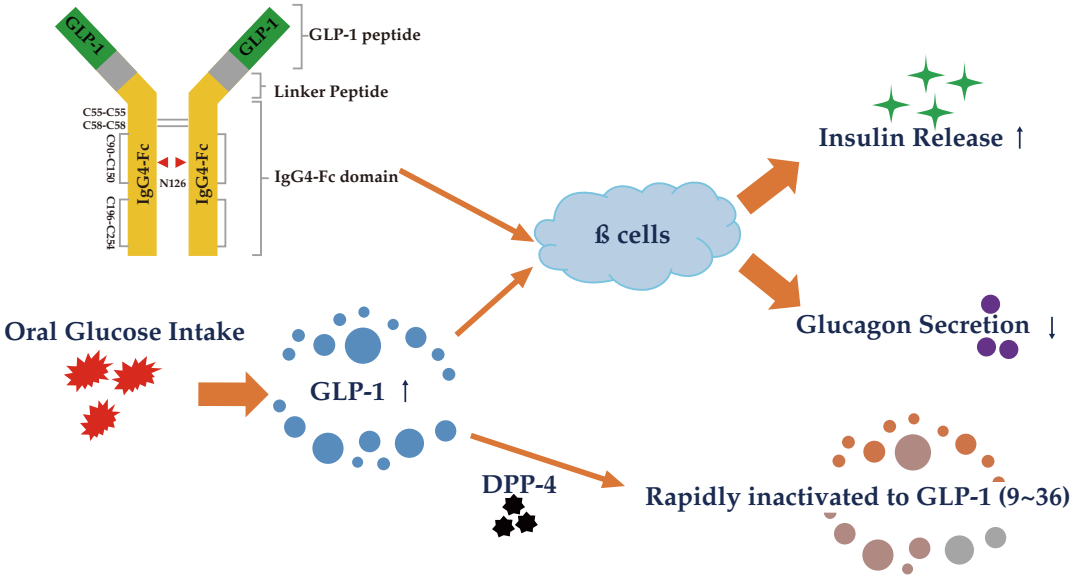
In 2014, Trulicity® was first launched in the United States, and was subsequently launched in many other countries and regions. In February 2019, Trulicity® was approved by the NMPA to launch in China. Dulaglutide was first added to the NRDL (2020 edition), which became effective on March 1, 2021. Major patents for dulaglutide will expire in December 2027, June 2029, and December 2025 in the United States, the EU and China, respectively. In 2021, the global sales of Trulicity® amounted to US$6.6 billion, while the sales in China amounted to RMB631.5 million according to the Frost & Sullivan Report.

Trulicity® is approved worldwide for the following indications: (i) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; and (ii) used to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Mechanism of action

Dulaglutide is a GLP-1 receptor agonist consisting of two identical disulfide-linked chains, each containing a modified analog of human GLP-1 (A2G, G16E, R30G) sequence covalently linked to a modified human IgG4 heavy chain fragment ("**Fc**") by a small linker peptide. Native GLP-1 is degraded by dipeptidyl peptidase-4 ("**DPP-4**") and cleared by the kidneys with a half-life of 1.5-2 minutes. Unlike native GLP-1, dulaglutide is not easily degraded by DPP-4 and has a larger molecular weight, which slows absorption and reduces renal clearance. These structural features allow dulaglutide to have a half-life of up to 4.7 days, supporting once-weekly subcutaneous administration. Furthermore, the dulaglutide molecular structure is designed to prevent Fcγ receptor-dependent immune responses and potentially reduce its immunogenicity.

The action of dulaglutide is similar to that of natural GLP-1. When the glucose concentration increases, it can increase the intracellular cAMP of pancreatic beta cells, promote insulin release, and inhibit glucagon secretion. It effectively reduces blood sugar with lower risks of hypoglycemia. It also reduces weight and has cardiovascular benefits.



Current therapies

As a second-line therapy in addition to diet and exercise in those patients who cannot achieve glycemic control on monotherapy metformin, the recommended starting dose of dulaglutide is 0.75 mg, once a week, and can be increased to 1.5 mg once a week to further improve glycemic control. If additional glycemic control is needed, the dose can be increased 3 mg, once a week, after at least four weeks on the 1.5 mg dose. If additional glycemic control is needed, the dose can be increased to the maximum dose of 4.5 mg, once a week, after at least four weeks on the 3 mg dose. The most common adverse reactions in clinical trials are gastrointestinal adverse reactions, including nausea, vomiting and diarrhea. These adverse reactions are usually mild or moderate and transient.

Potential market opportunities and competition

According to the Frost & Sullivan Report, the number of type 2 diabetes patients globally rose steadily from 434.6 million in 2017 to 479.0 million in 2021, with a CAGR of 2.5%, and is expected to increase to 585.5 million in 2030, with a CAGR of 2.3% from 2021 to 2030. In China, nearly 95% of diabetes are type 2 diabetes. The number of type 2 diabetic patients in China increased from 120.2 million in 2017 to 134.7 million in 2021, with a CAGR of 2.9%. Due to factors such as aging population and unhealthy life style, this number keeps growing and is estimated to increase to 167.7 million in 2030, with a CAGR of 2.5% from 2021 to 2030. In the United States, the therapies of type 2 diabetes include monotherapy, dual therapy, and combination injectable therapy. In China, for patients with very high blood sugar levels, physicians can prescribe insulin as first line therapy.

In healthy people, GLP-1 is secreted after eating, reducing glucose concentration by increasing insulin secretion and inhibiting glucagon release. The GLP-1 receptor agonist is a GLP-1 analog with most of the properties of GLP-1 and a longer half-life, and can be used to treat patients with type 2 diabetes whose GLP-1 secretion is impaired. GLP-1 drugs can be divided into the shortacting GLP-1 drugs and the long-acting GLP-1 drugs. According to 2021 Standards of Medical Care in Diabetes by American Diabetic Association, among patients with type 2 diabetes who have established atherosclerotic cardiovascular disease (ASCVD) or established kidney disease, GLP-1 receptor agonist with demonstrated cadiovascular disease (CVD) benefit is recommended as part of the glucose-lowering regimen. Compared to short-acting GLP-1 drugs, the advantages of long-acting GLP-1 drugs are better glycemic control, better medication compliance and suitable for patients with high susceptibility to gastrointestinal discomfort.

According to the Frost & Sullivan Report, the global sales revenue of long-acting GLP-1 market increased from US$2.8 billion in 2017 to US$12.2 billion in 2021, with a CAGR of 44.0%, and is expected to increase to US$39.7 billion in 2030, with a CAGR of 14.0% from 2021 to 2030. In China, GLP-1 receptor agonist market is basically dominated by foreign companies and there is an urgent need for GLP-1 receptor agonists safe, effective and reasonably priced to satisfy the domestic medical market for GLP-1 receptor agonists. According to the Frost & Sullivan Report, the sales revenue of China's long-acting GLP-1 market increased from nil in 2017 to RMB0.8 billion in 2021, and is expected to increase to RMB41.9 billion in 2030, with a CAGR of 54.2% from 2021 to 2030.

BA5101 was the first biosimilar of Trulicity® to initiate Phase 3 clinical trial. As of the Latest Practicable Date, there was no clinical-stage biosimilars of Trulicity® globally (outside of China). In China, there were five clinical-stage biosimilars of Trulicity® as of the same date. The details are set forth below:

Drug name/code	Company	Indication	Phase	First posted date
BA5101	**Our Group**	**Type 2 diabetes**	**Phase 3**	**2022-07-25**
SL209	SL Pharm	Type 2 diabetes	Phase 1	2022-04-26
14028	Dongguan HEC Biopharmaceutical R&D	Type 2 diabetes	Phase 1	2022-04-21
Recombinant GLP-1 receptor agonist	Lepu Medical	Type 2 diabetes	Phase 1(1)	2021-07-28
SAL015	Genekey Biotech | Suzhou Genemen Biotech	Type 2 diabetes	Phase 1(1)	2020-08-31

Note:

(1) Based on CDE information, phase 1 clinical trials of recombinant GLP-1 receptor agonist and SAL015 have been completed.

Source: Frost & Sullivan Report

BA5101 is potentially one of the first-to-market biosimilar to Trulicity® in China. We believe BA5101 will be well positioned to compete in the market and gain a leading market share following its launch.

Summary of clinical development history and results

Clinical development

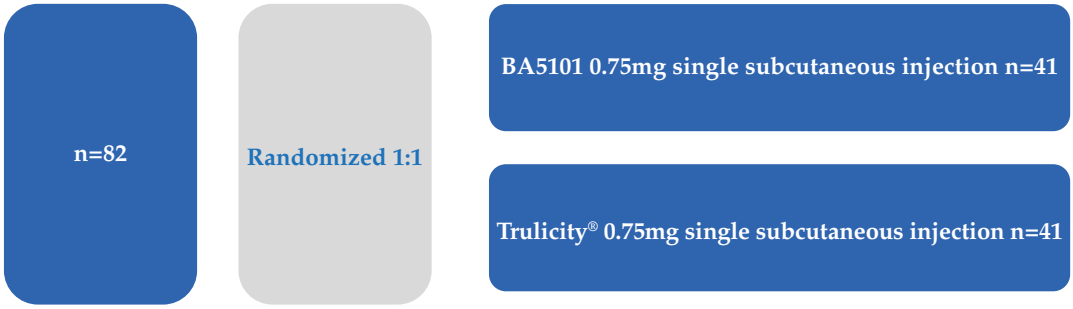
Ongoing Phase 3 clinical trial

Study design. The Phase 3 clinical trial of BA5101 is a multi-center, randomized, open, parallel and positive-controlled clinical study in Chinese adult patients with type 2 diabetes to compare the efficacy, safety, immunogenicity and PK characteristics of BA5101 and Trulicity®.

Efficacy, safety, immunogenicity and PK. As of the Latest Practicable Date, the Phase 3 clinical trial in China was ongoing, and thus the results were not yet available.

Phase 1 clinical trial

Study design. The Phase 1 clinical trial was a single-center, randomized, open, parallel, active-controlled study, comparing the PK, safety and immunogenicity of BA5101 and Trulicity® in healthy Chinese male subjects. The studies consisted of a pre-trial and a formal trial. 24 healthy male subjects were enrolled for the pre-trial, and the subjects were randomly divided into the BA5101 group and the Trulicity® group in a 1:1 ratio. We enrolled 82 healthy male subjects in the formal trial, and 41 in the BA5101 group and 41 in the Trulicity® group.



Safety endpoints were (i) vital signs; (ii) physical examination; (iii) laboratory tests; (iv) 12-lead ECG; and (v) adverse events.

Pharmacokinetic primary endpoints included $AUC_{0-\infty}$ and C_{max}., and secondary endpoint included AUC_{0-t}, T_{max}, CL/F, λ_z, $t_{1/2}$, and V_z/F.

Immunogenicity endpoints included ADA- and NAb-positive rates, and corresponding antibody titers.

PK, safety and immunogenicity. We have completed the pre-trial and the formal trial of the Phase 1 clinical trial of BA5101 in April 2022. The geometric mean ratio and 90% CI of the PK parameters after a single subcutaneous injection of 0.75mg BA5101 or Trulicity® all fall in the pre-specified equivalence range (80.00%~125.00%). The safety and immunogenicity results indicate that a single subcutaneous injection of BA5101, 0.75mg in healthy Chinese male adult subjects was safe and well tolerated, with a safety spectrum similar to Trulicity®.

Pre-clinical research

In the similarity study between BA5101 and Trulicity®, their physicochemical properties and biological activities are highly similar. The results of the head-to-head acceleration experiments of the two showed that the degradation trends after three months acceleration were similar and had similar stability profiles.

The affinity and function of BA5101 and Trulicity® for GLP-1R, FcRn and Fcγ receptors are similar and neither binds to C1q and have no antibody-dependent cell-mediated cytotoxicity ("**ADCC**") and CDC activities. In a pharmacodynamic study of spontaneously type II diabetic Zucker Diabetic Fatty ("**ZDF**") rats, the same dose of BA5101 and Trulicity® had similar hypoglycemic effects.

In terms of single-dose pharmacokinetics, BA5101 and Trulicity® C_{max}, AUC and other pharmacokinetic parameters were similar. In multiple doses, there was no significant difference in the main pharmacokinetic parameters between BA5101 and Trulicity® after the first and last doses.

In the repeated administration test, female and male monkeys in BA5101 group experienced decreased body weight, decreased food intake, atrophied bone marrow and subcutaneous fat cells and decreased lymphocytes in thymus, spleen and lymph nodes. The weight/coefficient of thymus in monkeys in each group decreased and the lymphocytes in thymus, spleen and lymph nodes decreased. The above changes were also seen in the Trulicity® group at the same dose and the proportion and extent were basically the same. Toxicity showed that BA5101 did not accumulate significantly in cynomolgus monkeys and there was no significant gender difference in exposure, which increased in proportion to the dose. Compared with the same dose (10 mg/kg) of Trulicity®, the ratios of C_{max} and $AUC_{0\text{-}96h}$ after the first dose were 88.0% and 96.5%, respectively, and the ratios of C_{max} and $AUC_{0\text{-}96h}$ after the last dose were 98.2%, respectively and 108.8%, respectively.

Pre-clinical studies have shown that BA5101 and Trulicity® have biosimilarity in pharmacy, pharmacological pharmacodynamics, pharmacokinetics and toxicology.

Material communications and next steps

We received the IND approval for BA5101 from the CDE in September 2021. As of the Latest Practicable Date, we were conducting the BA5101's Phase 3 clinical trial in China. In addition, we plan to have a communication meeting with the CDE to confirm the Phase 3 clinical trial design. We are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA5101. Additionally, we plan to have regulatory communications with the FDA and submit the IND of BA5101 to the FDA in the first half of 2023 and initiate the Phase 1 clinical trial in the second half of 2023.

Collaboration arrangements and commercialization plans

We intend to manufacture BA5101, once approved, at our Yantai Site for distribution in China. See "— Manufacturing" in this section for further details on the technologies utilized in the Yantai Site. Our marketing efforts will primarily target hospitals across China. We will also explore the possibility of expanding the commercialization of BA5101 to overseas markets, focusing on countries where access to Trulicity® and its biosimilars may be challenging for a significant portion of the affected population. In order to commercialize BA5101 in those countries, we plan to identify and enter into license and commercialization agreements with reputable local partners in due course.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA5101.

OUR INNOVATIVE ANTIBODY PORTFOLIO

Overview

We strategically develop our innovative antibody candidates to focus on novel antibodies with significant market potential. Our innovative antibody portfolio currently includes eight innovative antibody candidates. For example, our BA1105 targets a larger applicable patients pool and we believe it is a potential best-in-class drug candidate for the treatment of gastric cancer with Claudin 18.2 expression because it demonstrates stronger anti-tumor activities in *in vitro* and *in vivo* models compared to other clinical-stage drug candidates with the same target for the treatment of gastric cancer. Our BA1106, based on its pre-clinical trial data, shows strong efficacy for both early-stage and late-stage tumors, and it demonstrates a good synergetic effect when used in combination with an anti-PD-1 antibody and inhibits immunosuppression in tumor microenvironment without blocking the IL-2 signaling pathway. Our LY-CovMab, an innovative antiviral drug candidate for the treatment of COVID-19, is currently under Phase 2 clinical trial.

Our Core Product: LY-CovMab

Overview

We are developing LY-CovMab, which is a fully human monoclonal antibody manufactured by recombinant technology and used to counteract COVID-19. We began developing LY-CovMab in February 2020 and are conducting Phase 2 clinical trial in China. We expect to complete LY-CovMab's Phase 2 clinical trial at the earliest in 2023. However, given that the therapeutic area of LY-CovMab is infectious disease, the progress of its clinical trials is subject to various factors, such as the infectivity and severity of the virus, the virus variants which are spreading, and the patient enrollment process. Based on our preliminary clinical findings, LY-CovMab could be a SARS-CoV-2 neutralizing antibody candidate for both of prevention and treatment of COVID-19. We plan to launch LY-CovMab initially in China after we receive regulatory approval and may also explore the possibility of expanding the commercialization of LY-CovMab to other overseas markets. According to *in vitro* virus neutralization activity data, LY-CovMab has a neutralizing effect on Alpha, Delta, Gamma, Lambda variants, and has a limited neutralization effect on Omicron variant. The SARS-CoV-2 B.1.1.529 (Omicron) variant contains 15 mutations of the receptor-binding domain (RBD) and might evade RBD-targeted neutralizing antibodies according to the article "Omicron escapes the majority of existing SARS-CoV-2 neutralizing antibodies" published in *Nature* authored by Cao, Y., Wang, J., Jian, F. et al in 2022. For more details, see "Risk Factors — Risks relating to the commercialization of our drug candidates — We may not be able to successfully commercialize LY-CovMab, one of our Core Products, or BA-CovMab, which may negatively affect our business, results of operations and business prospects".

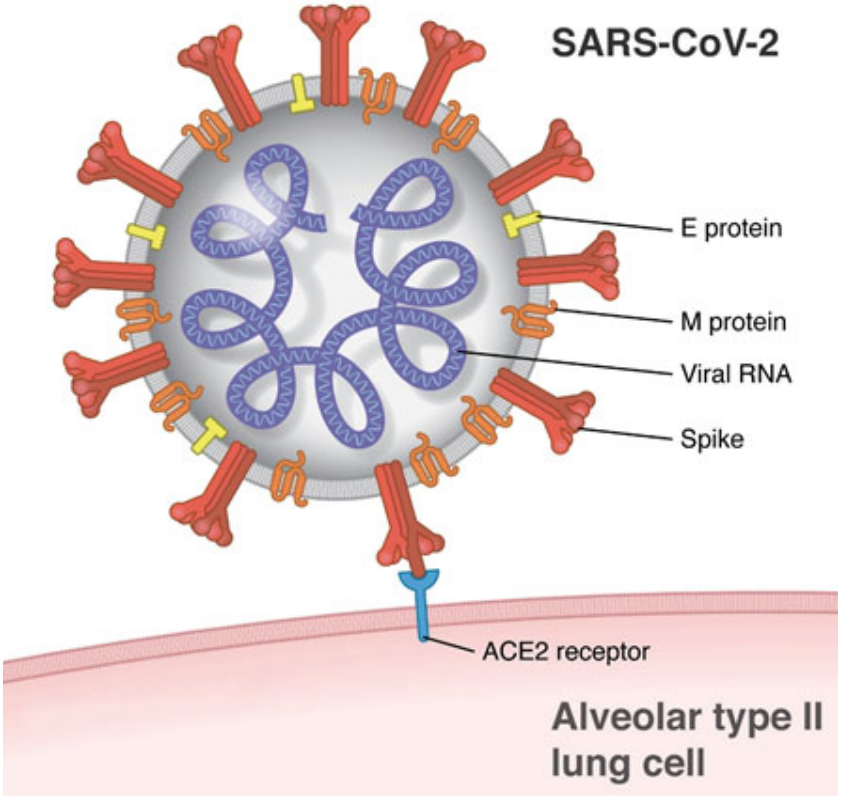
Mechanism of action

LY-CovMab is a human monoclonal antibody discovered by human antibody transgenic mouse and phage display technology and used to combat COVID-19 pandemic. SARS-CoV-2 is an enveloped single positive-strand RNA virus and the spike protein ("**S**

protein") on the viral membrane envelope is a viral factor that mediates attachment to cells and fusion of the viral and cellular membrane. SARS-CoV-2 uses human angiotensin-converting enzyme 2 ("**hACE2**") to enter host cells. Cellular entry is achieved by the homotrimeric S-mediated virus-receptor entry binds ACE2 via its RBD followed by virus-host membrane fusion (see the diagram 1 below). Specifically, S protein functions through the S1 and S2 subunits respectively: (i) the S1 subunit comprises the RBD domain, which mediates attachment to target cells; and (ii) the S2 subunit, which contains the fusion peptide and functions in membrane fusion. (see the diagram 2 below).

Neutralizing antibody was used as an important tool to fight against the SARS-CoV-2 pandemic by preventing the virus from entering the host cells. LY-CovMab targets the RBD of SARS-CoV-2 S protein, and blocks the binding of RBD to human ACE2, thereby blocking virus invasion and exerting its antiviral effects (see the diagram 3 below). The specific mechanism of action is shown in the diagrams below.

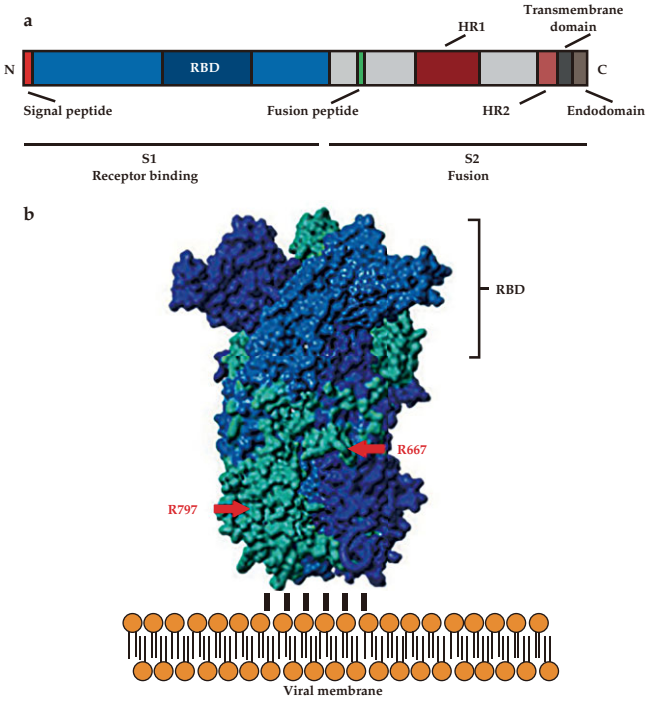
Diagram 1: Schematic diagram of the structure of SARS-CoV-2



Source: https://janewhitney.com/histology

The S protein (Red), M protein (Orange), E protein (Yellow), Viral RNA (Blue) and ACE2 receptor (Light blue) are indicated. The S protein mediates attachment to cells through Spike-ACE2 engagement.

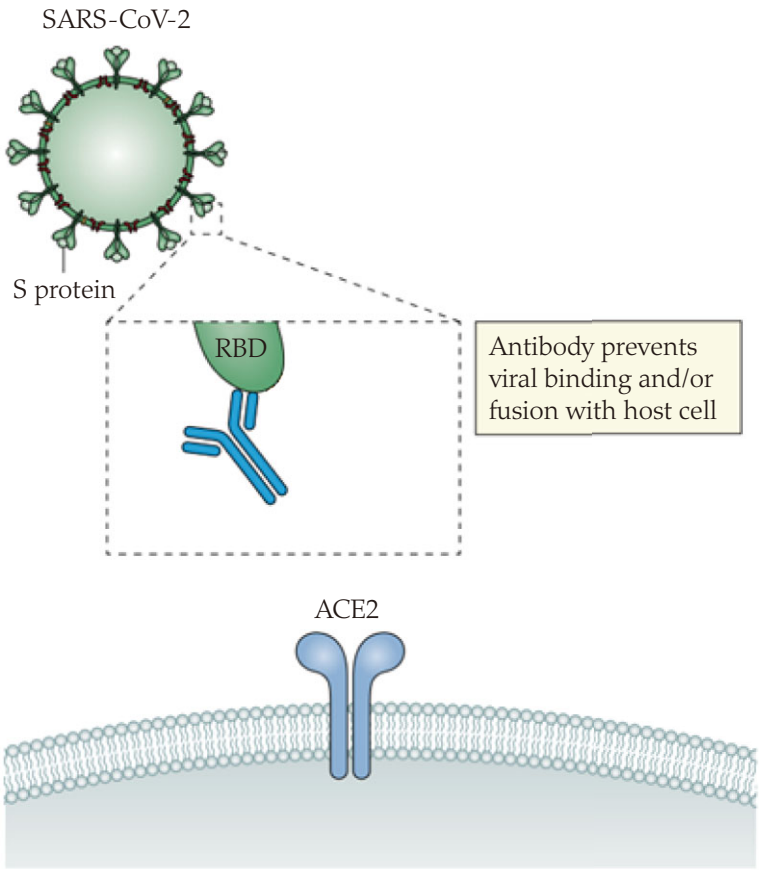
Diagram 2: Schematic diagram of the structure and domain architecture of S protein



Source: COVID19: an announced pandemic. doi: 10.1038/s41419-020-02995-9

S protein contains subunit S1 and S2. The S1 subunit comprises the RBD domain, which mediates attachment to target cells. The S2 subunit, which contains the fusion peptide, HR1, HR2, Transmembrane, Endodomain and functions in membrane fusion. The spike glycoprotein decorated on the viral membrane envelope is a trimer with RBDs to capture ACE2.

Diagram 3: Inhibition of SARS-CoV-2-target cells engagement by neutralizing monoclonal antibodies



Source: Neutralizing monoclonal antibodies for treatment of COVID-19. doi: 10.1038/s41577-021-00542-x

Neutralizing monoclonal antibodies (like LY-CoVMab) can bind to the RBD of S protein, block the binding of RBD to ACE2 and inhibit virus invasion.

Diagram 4: The Cryo-EM structures of LY-CovMab in complex with SARS-CoV-2 S protein

Source: Structure and function analysis of a potent human neutralizing antibody CA521 FALA against SARS-CoV-2. doi: 10.1038/s42003-021-02029-w.

Green: Fragment Variable of LY-CovMab, Magenta: RBD, Blue: other part of the Spike protein.

Potential market opportunities and competition

As the pathogen of COVID-19, SARS-CoV-2 is continuing to spread and cause the global pandemic with millions of confirmed COVID-19 cases including over 6.0 million deaths as of the Latest Practicable Date according to the data of the WHO. Patients are still facing few options for effective medications. According to the Frost & Sullivan Report, the disease is more likely to occur in older people. The CDC reported that although individuals older than age 65 comprise 17% of the total population in the United States, they make up 31% of COVID-19 infections, 45% of hospitalizations, 53% of intensive care unit admissions, and 80% of deaths caused by this infection.

Pharmacologic treatment for COVID-19 mainly includes corticosteroids, anti-viral agents, and neutralizing antibodies; however, there is currently no direct comparisons of the various therapeutics in trials. According to "Therapeutics and COVID-19: living guideline" updated in September 2022 by WHO, choices for patients with non-severe COVID-19 and for those with severe or critical COVID-19 depend on availability of the drugs, routes of administration, duration of treatment, etc. The recommendation level mentioned in the guideline can be categorized into strong recommendation and conditional recommendation. Strong recommendation for patients with severe or critical COVID-19 includes systemic corticosteroids, interleukin-6 receptor blockers (tocilizumab or sarilumab) and JAK inhibitor baricitinib. Conditional recommendation includes remdesivir in patients with severe COVID-19. For non-severe COVID-19 patients, strong recommendation includes nirmatrelvir and ritonavir, and conditional recommendation includes molnupiravir and remdesivir.

Neutralizing antibody is one of the most promising therapies for the treatment of COVID-19. Neutralizing antibodies have obtained emergency use authorization or approved not only for the treatment of mild-to-moderate or severe COVID-19, but also for the pre-exposure prevention of COVID-19. As of the Latest Practicable Date, there was a total of six COVID-19 neutralizing antibodies that were authorized for use under the EUA in the United States and/or approved by the EMA in Europe and over 60 clinical-stage COVID-19 neutralizing antibodies being developed globally. The following table illustrates the competitive landscape of COVID-19 neutralizing antibodies that were authorized for use under the EUA in the U.S. and/or approved by the EMA in Europe as of the Latest Practicable Date:

Drug name/code	Company	Status	Indication	Approval date	Authority	Drug type	Cost per treatment cycle (US$)	2021 sales revenue (million US$)
Regdanvimab (Regkirona)	Celltrion	Marketed	COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021 -11 -12	EMA	mAb	NA	37.6 (2021 H1)
REGEN-COV (Ronapreve)	Roche | Regeneron	Marketed	COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021 -11 -12	EMA	Combination of 2 mAbs	2,000	5,828
Sotrovimab (Xevudy)	GSK | Vir	Marketed	COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021-12-17	EMA	mAb	NA	1,317
Evusheld	AstraZeneca	EUA	Pre-exposure prophylaxis for prevention of COVID-19	2021 -12 -08	FDA	Combination of 2 mAbs	NA	85
		Marketed	Prevention of COVID-19 in adults and adolescents from 12 years of age weighing at least 40 kg before potential exposure	2022 -03 -24	EMA			
Tocilizumab (Actemra)	Genentech	EUA	Hospitalized adult and pediatric (two years of age and older) COVID-19 patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation	2021 -06 -24	FDA	mAb	3,159.4	NA
		Marketed	Severe COVID-19 in adults receiving systemic corticosteroids and supplemental oxygen or mechanical ventilation	2021 -12 -07	EMA	mAb		
Bebtelovimab	Eli Lilly	EUA	Mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19 and without alternative treatment options	2022 -02 -11	FDA	mAb	NA	NA

Source: Frost & Sullivan Report

The following table illustrates the competitive landscape of marketed and clinical-stage COVID-19 antibodies in China as of the Latest Practicable Date:

Drug name/code	Company	Status	Indication	NMPA approval/ First posted date	Drug type	Annual cost per patient (RMB)	2021 China sales revenue (million RMB)
Amubarvimab/ Romlusevimab (BRII-196/BRII-198)[1]	Brii Biosciences	Marketed	Adult and pediatric ((12-17 years of age weighing at least 40 kg) COVID-19 patients with mild or moderate symptoms and a high risk of progressing to severe COVID-19	2021-12-08	Combination therapy of 2 mAbs	NA	NA
Meplazumab	Jiangsu Pacific Meinuoke Bio Pharmaceutical	Phase 2/3	COVID-19	2021-11-09	mAb	NA	NA
SCTA01	Sinocelltech	Phase 2/3	Severe COVID-19	2020-11-25	mAb	NA	NA
BDB-001	Staidson (Beijing) Biopharmaceuticals	Phase 2/3	Severe COVID-19	2020-06-29	mAb	NA	NA
LY-CovMab	**Our Group**	**Phase 2**	**COVID-19**	**2021-08[2]**	**mAb**	**NA**	**NA**
Etesevimab JS016	Shanghai Junshi Bioscience	Phase 2	COVID-19	2021-06-18	mAb	NA	NA
MW33	Mabwell (Shanghai) Bioscience	Phase 2	Mild or moderate COVID-19	2020-11-13	mAb	NA	NA
IBI314	Innovent Biologics	Phase 1/2	Mild or moderate COVID-19	2021-12-29	mAb	NA	NA
HFB30132A	HiFiBiO Therapeutics	Phase 1	COVID-19	2022-03-11	mAb	NA	NA
BA-CovMab	**Our Group**	**Phase 1**	**COVID-19**	**2022-09[3]**	**mAb**	**NA**	**NA**

Notes:

(1) Based on the company's announcement and the Chinese patent search, the relevant patent for BRII-196/BRII-198 is expected to expire in 2041 in China.

(2) LY-CovMab was granted approval to commence the Phase 2 clinical trial in China in August 2021.

(3) BA-CovMab was granted approval to commence the Phase 1 clinical trial in China in September 2022.

Source: Frost & Sullivan Report

The following table illustrates the competitive landscape of other treatment options for COVID-19 as of the Latest Practicable Date:

Drug name/code	Company	Status	Indication	Approval date	Authority	Drug type	2021 sales revenue (million US$)
Remdesivir (Veklury)	Gilead	Marketed Marketed	In adults and pediatric patients (28 days of age and older and weighing at least 3kg) with positive results of direct SARS-CoV-2 viral testing with non-severe COVID-19 at highest risk of hospitalization and severe COVID-19	2020-10-22 2021-12-17	FDA EMA	Antiviral agent (chemical drug)	5,565.0
Baricitinib[1] (Olumiant)	Eli Lilly	Marketed	COVID-19 in hospitalized adults requiring supplement oxygen, non-invasive or invasive mechanical ventilation, or ECMO	2018-05-31	FDA	Antiviral agent (chemical drug)	1,115.1
Nirmatrelvir -ritonavir (Paxlovid)	Pfizer	EUA Marketed	COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	2021-12-22 2022-01-28	FDA EMA	Antiviral agent (chemical drug)	76.0
Molnupiravir (Lagevrio)	Merck	EUA	Non-severe COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death	2021-12-23	FDA	Antiviral agent (chemical drug)	NA

Notes:

(1) Baricitinib is recommended to be administrated in combination with corticosteroids and IL-6 receptor blocker (tocilizumab) to patients with severe or critical COVID-19.

(2) This table only includes COVID-19 drugs that are authorized for use under EUA by FDA and/or approved by FDA and/or EMA as of the Latest Practicable Date. Systemic corticosteroids are not approved officially for COVID-19 and thus are not included in the table.

Source: Frost & Sullivan Report

Although the SARS-CoV-2 neutralizing antibodies and vaccines have offered both therapeutic and preventive benefits, a large number of people are still suffering the terrible pandemic, which causes an ever-surging number of patients with COVID-19, creating a large unmet medical need. There is an urgent need for therapeutic interventions to combat the COVID-19 caused by SARS-CoV-2. Neutralizing antibodies are an important tool that can effectively fight the coronavirus. LY-CovMab is a human neutralizing antibody that can effectively inhibit pseudovirus and authentic virus infection *in vitro* by interfering the virus attaches to the host cell. Our study identifies LY-CovMab as an excellent neutralizing antibody against SARS-CoV-2 with the following advantages: (i) direct competitive binding with ACE2, binding all three RBDS of one spike simultaneously and one spike and one IgG molecule bivalent binding to one spike protein trimer; (ii) showing promise as an effective intervention to the COVID-19 pandemic caused by SARS-CoV-2; and (iii) potent neutralizing ability, the low risk of antibody-dependent enhancement ("**ADE**") and long half-life.

LY-CovMab shows significant therapeutic efficacy in a newly established SARS-CoV-2 susceptible mice. LY-CovMab treatment resulted 34914-fold and 693-fold reduction of viral titers in the lungs and trachea at three days post infection, respectively. Histopathological examination also showed significant improvement in the lung.

LY-CovMab overcomes the potential risk of ADE for antibody therapeutics against SARS-CoV-2 infection. By introducing IgG4 subtype and FALA mutation the affinity of LY-CovMab to Fc Receptors, C1q or phagocytosis of macrophages induced by LY-CovMab was modified. Furthermore, pharmacokinetic analysis performed in mice and rhesus monkeys revealed that LY-CovMab was very stable and had a half-life of 9.5 ± 4 days in mice and 9.3 ± 5 days in rhesus monkeys.

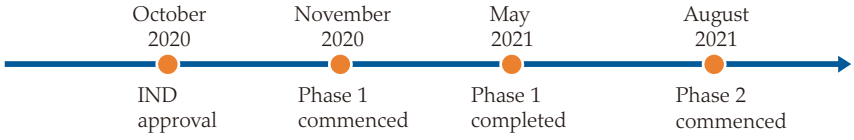
The 3D structure derived from 614,999 particles of SARS-CoV-2/ LY-CovMab complex shows that all three RBDs of the S protein trimers are up with Fab bound asymmetrically. Recent research shows that ACE2 binding induces the transition of RBD from close to open conformation. LY-CovMab may use a mechanism similar to ACE2 and promote the opening of other closed RBDs to facilitate the binding of LY-CovMab after binding the "open" RBD.

Summary of clinical development history and results

As of the Latest Practicable Date, we were conducting Phase 2 clinical trial for LY-CovMab in China.

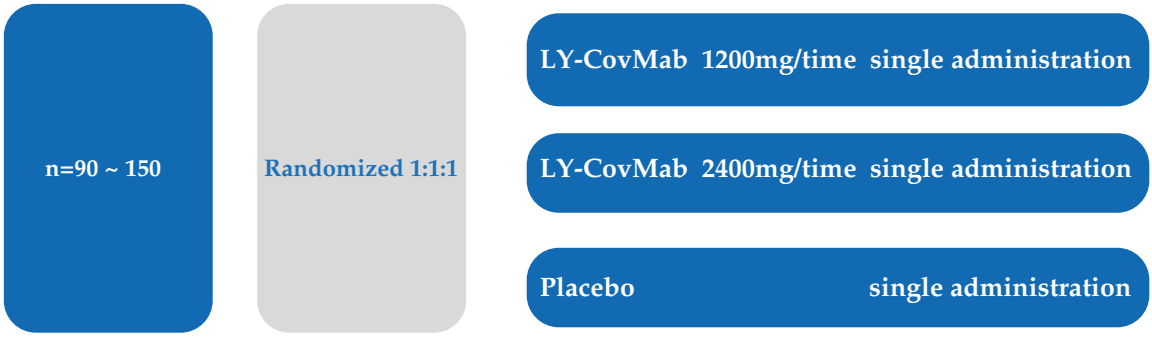
Clinical development

The chart below summarizes the development timeline of LY-CovMab:



Ongoing Phase 2 clinical trial

Study design. The ongoing Phase 2 clinical trial of LY-CovMab is a multi-centered, randomized, double-blind, single-dose, placebo-controlled design to evaluate the efficacy, safety, pharmacokinetics and immunogenicity of LY-CovMab injection in the treatment of patients with mild-to-moderate COVID-19. There are three groups, namely 1200 mg/time dose group, 2400 mg/time dose group and placebo group. Each group plans to include 30 to 50 subjects, with a total of 90 to 150 subjects. The subjects will complete the screening work within three days before randomization. The clinical efficacy will be observed to the 29th day and the safety follow-up will end on the 99th day.



The primary endpoint is the time-weighted average change from baseline in viral load (from the first day to the seventh day, with the first day being the baseline).

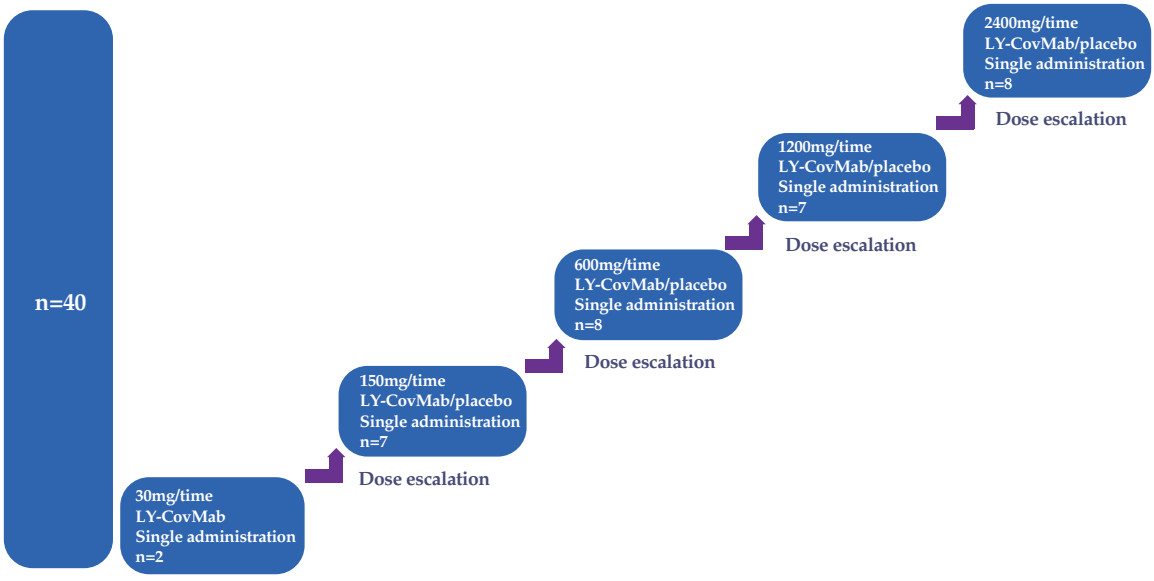
The secondary endpoints include (i) the proportion of patients who developed severe or critical illness (ii) time to negative nucleic acid test for SARS-CoV-2; (iii) change from baseline in viral load; (iv) time-weight average change from baseline in viral load; (v) negative rate of nucleic acid test for SARS-CoV-2; (vi) symptom improvement and recovery; and (vii) all-cause mortality.

Efficacy, safety, PK and immunogenicity. As of the Latest Practicable Date, the Phase 2 clinical trial for LY-CovMab remained ongoing, and thus its efficacy, safety, PK and immunogenicity findings were not yet available.

Phase 1 clinical trial

Based on the data collected and analyzed in the Phase 1 clinical trial, we concluded that (i) the PK characteristics of LY-CovMab were positively correlated with dosage; and (ii) LY-CovMab of different dosages showed favorable tolerability.

Study design. The Phase 1 clinical trial of LY-CovMab was a randomized, double-blind, single ascending dose, placebo-controlled study included 42 randomized Chinese healthy adults aged 18 to 45 years old from the Second Hospital of Anhui Medical University of China. The purpose of this study was to assess safety, tolerability, pharmacokinetics and immunogenicity of LY-CovMab in Chinese healthy adults. In terms of dosing details, two subjects received 30 mg LY-CovMab, seven subjects received 150 mg LY-CovMab, eight subjects received 600 mg LY-CovMab, seven subjects received 1200 mg LY-CovMab, eight subjects received 2400 mg LY-CovMab, and eight subjects received placebo. Each subject received only one corresponding dose as a single intravenous infusion. Follow-up was for up to 99 days after infusion. During the study, blood samples were collected for pharmacokinetic and immunogenic analyses, and participants' vital signs, physical examination, 12-lead electrocardiogram (ECG), laboratory tests, and adverse events were recorded. Phase 1 clinical trial was completed on May 18, 2021.

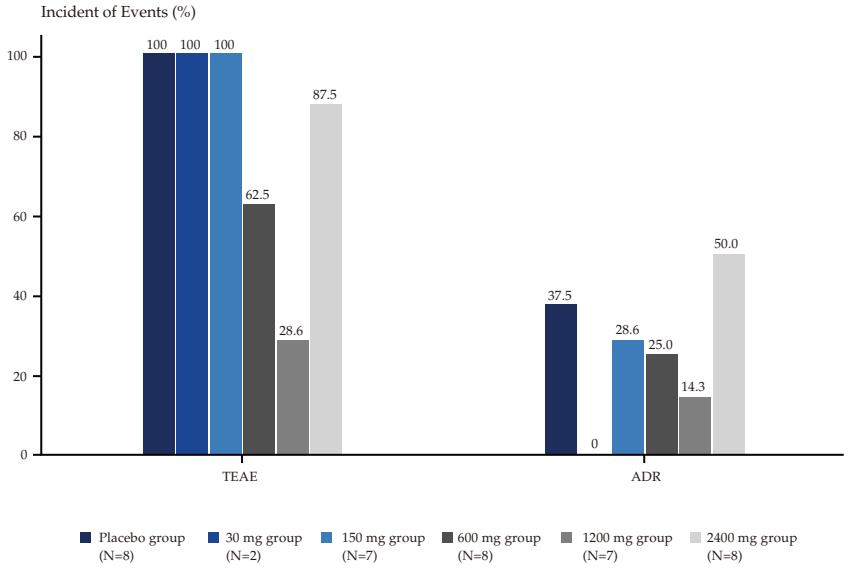


The safety endpoints included (i) vital signs; (ii) physical examination; (iii) laboratory tests (blood routine, blood biochemistry, urine routine and coagulation function); (vi) 12-lead ECG; and (v) adverse events.

Pharmacokinetic endpoints included (i) C_{max}; (ii) T_{max}; (iii) area under the drug-time curve from 0 to the last quantifiable concentration time point ("**$AUC_{0\text{-}last}$**"); (iv) $AUC_{\_\%Extrap}$; (v)$AUC_{0\text{-}\infty}$; (vi) CL; (vii) $t_{1/2}$; and (viii) V_d.

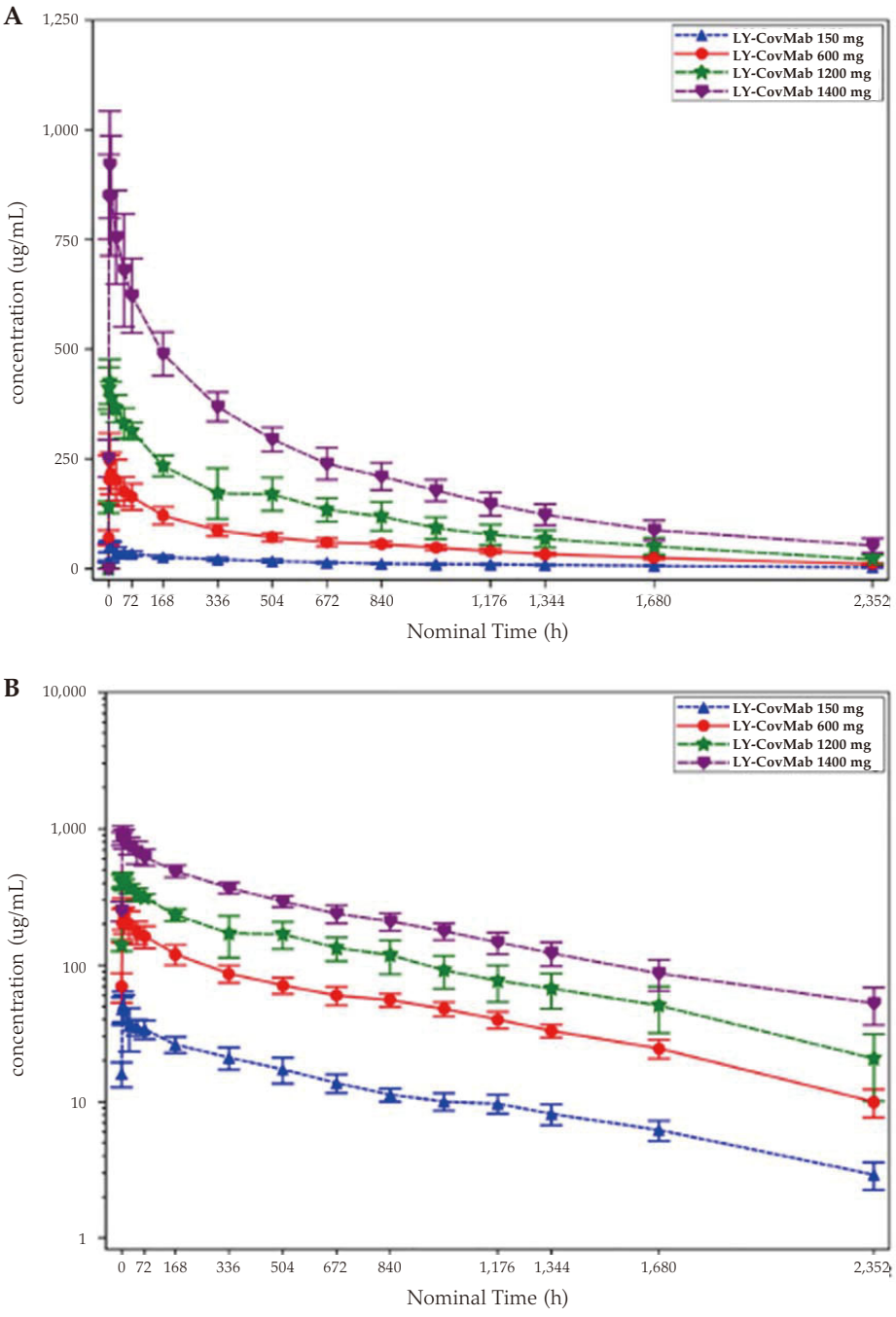
Immunogenicity was also evaluated based on the incidence rate of ADA-positive results, NAb-positive results and the corresponding antibody titers.

Safety. 77.5% participants reported 99 TEAEs. 30.0% participants reported 18 ADRs. Among TEAEs, 72.5% participants with 90 events were classified as grade 1 and 12.5% participants with 9 events were classified as grade 2. Most TEAEs were recovered or resolved without taking action. There were no deaths, withdrawals due to TEAEs, and no SAE, serious drug-related TEAEs, or other significant adverse events occurred during the study. The following chart sets forth the safety findings in more detail:



TEAE: treatment-emergent adverse events
ADR: study drug-related TEAE

PK. The 95% confidence interval ("**CI**") of the point estimates contains 1. Therefore, exposure parameters (Cmax and AUC) were considered to increase in an approximately proportional manner as the dose increased. The following diagram sets forth the PK findings in more detail:



Immunogenicity. ADA tested positive in 12.5% of the participants (5/40). One subject in the 1200 mg group was tested ADA-positive before dosing and was not considered to be caused by LY-CovMab. The ADA positivity did not impact on the serum concentration or safety profile of LY-CovMab. This will be confirmed with neutralizing antibody analysis in future studies. The following chart sets forth the immunogenicity findings in more detail:

Summary statistics of immunogenicity of LY-CovMab over time (immunogenicity set N = 40)

Parameter	Visit	Placebo (N=8)	LY-CovMab 30mg (N=2)	LY-CovMab 150mg (N=7)	LY-CovMab 600mg (N=8)	LY-CovMab 1,200mg (N=7)	LY-CovMab 2,400mg (N=8)
Anti-LY-CovMab antibodies	Day 1 – Predose						
	Negative	8 (100.0%)	2 (100.0%)	7 (100.0%)	8 (100.0%)	6 (85.7%)	8 (100.0%)
	Positive	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)
	Day 15						
	Negative	8 (100.0%)	2 (100.0%)	7 (100.0%)	8 (100.0%)	7 (100.0%)	8 (100.0%)
	Positive	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Day 29						
	Negative	8 (100.0%)	2 (100.0%)	7 (100.0%)	8 (100.0%)	6 (85.7%)	8 (100.0%)
	Positive	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Day 43						
	Negative	8 (100.0%)	2 (100.0%)	7 (100.0%)	8 (100.0%)	5 (71.4%)	8 (100.0%)
	Positive	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Day 57						
	Negative	8 (100.0%)	2 (100.0%)	6 (85.7%)	7 (87.5%)	6 (85.7%)	8 (100.0%)
	Positive	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (12.5%)	0 (0.0%)	0 (0.0%)
	Day 71						
	Negative	8 (100.0%)	2 (100.0%)	7 (100.0%)	8 (100.0%)	5 (71.4%)	8 (100.0%)
	Positive	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)
	Day 99						
	Negative	8 (100.0%)	0 (0.0%)	5 (71.4%)	7 (87.5%)	4 (57.1%)	7 (87.5%)
	Positive	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (12.5%)	1 (14.3%)	1 (12.5%)

The denominator was the number of subjects within each group.

Pre-clinical research

We commenced the research and development of LY-CovMab in February 2020. Pre-clinical testing and studies included:

- Pre-clinical PD/PK studies. Results of pre-clinical PD studies showed that LY-CovMab had high affinity with RBD *in vitro*, effectively blocked the binding of ACE2 to RBD, had a clear virus neutralization effect and also had excellent virus neutralization activity *in vivo*. The results of the safety pharmacology test in rhesus monkeys showed that LY-CovMab at doses of 50, 200 and 800 mg/kg had no significant effect on the central nervous system, cardiovascular system and respiratory system. In rhesus monkey pharmacokinetic study, following a single-dose of LY-CovMab at 15, 60, 240 mg/kg, t1/2 were 224, 275, 325 h; AUC_{last} were 70.1, 335 and 1210 h*mg/mL, respectively.

- Pre-clinical toxicology studies. Pre-clinical toxicology studies demonstrated that LY-CovMab was unlikely to cause ADE effects. LY-CovMab had no cross-reactivity with normal human tissues and rhesus monkey tissues. LY-CovMab at 10 mg/mL did not induce rabbit RBC (red blood cells) aggregation or hemolysis. In the single-dose extended toxicity study and 4-week multiple-dose toxicity study in rhesus monkey with LY-CovMab doses of 50, 200, 800 mg/kg, no drug-related abnormal changes have been observed in all observed parameters. During the toxicity study, no anti-LY-CovMab antibody was detected, and LY-CovMab showed no local irritation reaction and immunotoxicity. Within the dose range of 50-800 mg/kg, serum exposure of LY-CovMab showed no apparent gender difference and increased generally dose proportionally, and no obvious accumulation was noted after 4-week repeated dosing. In the 4-week multiple-dose toxicity study, rhesus monkeys received 50, 200, 800 mg/kg LY-CovMab by intravenous injection, once a week for 5 consecutive doses, followed by a 4-week recovery phase, the NOAEL was 800 mg/kg, where the $AUC_{0\text{-}168h}$ was 1710 h*mg/mL for females and 1820 h*mg/mL for males after the 4th dosing.

In summary, LY-CovMab has demonstrated definite virus-neutralizing activity, good pharmacokinetic and safety profiles. The non-clinical pharmacology and toxicology profiles supported the entry of LY-CovMab into clinical trials for further investigation of LY-CovMab. We submitted the IND application to the NMPA for LY-CovMab and received approval to commence clinical trial in October 2020.

Material communications and next steps

We received the IND approval from the CDE in October 2020. According to our PRC Legal Adviser, we have obtained all necessary approvals from the NMPA and the CDE to proceed with the LY-CovMab Phase 2 clinical trial and the NMPA and the CDE had no objection for us to commence a Phase 2 clinical trial as planned.

On January 27, 2021 and June 24, 2021, we further communicated with the CDE on the Phase 2 clinical trial design, and obtained the consent of the CDE on the Phase 2 clinical trial design. The CDE had no objection for us to commence the Phase 2 clinical trial.

Other than the above, we have not had any material regulatory communications with the NMPA or CDE for LY-CovMab, and we are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of LY-CovMab.

We continue to conduct our Phase 2 clinical trial for LY-CovMab in China and will evaluate and submit the study results from Phase 2 clinical trial to the relevant regulators when available in order to obtain regulatory approvals. We will discuss with the CDE on the Phase 3 clinical trial design of LY-CovMab after the completion of the Phase 2 clinical trial.

See "— Intellectual property" for details of intellectual properties which we have registered, maintained, applied for or intend to apply for with respect to LY-CovMab.

Collaboration arrangements and commercialization plans

Assuming that we successfully obtain regulatory approval for LY-CovMab, we intend to begin commercial manufacturing of LY-CovMab for distribution initially in the PRC. We may utilize our dedicated in-house sales and marketing team and cooperate with business partners including promoters and distributors to commercialize LY-CovMab in China. We will develop a detailed business plan for LY-CovMab after the completion of Phase 2 clinical trial, and explore business cooperation opportunities in China and overseas based on Phase 2 clinical results.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING LY-CovMab.

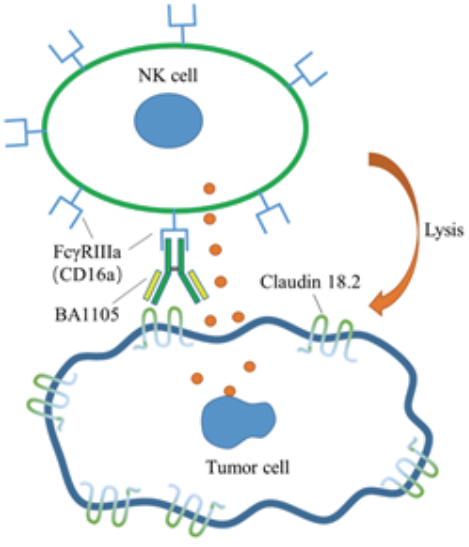
BA1105

Overview

We are developing BA1105, which is a recombinant anti-Claudin 18.2 fully human IgG1 monoclonal antibody that introduces amino acid site-directed mutations through the Fc region to enhance the ADCC effect. We began developing BA1105 in June 2019 and are conducting Phase 1 clinical trial in China. Based on our pre-clinical and preliminary clinical findings, BA1105 has the potential to become the best targeted drug for the similar treatment of metastatic pancreatic cancer, advanced gastric cancer and adenocarcinoma of the esophagogastric junction. We plan to launch BA1105 initially in China after we receive regulatory approval and may also explore the possibility of expanding the commercialization of BA1105 to other overseas markets.

Mechanism of action

BA1105 is a recombinant anti-Claudin 18.2 fully human IgG1 monoclonal antibody, which enhances tumor-killing efficacy by enhancing ADCC effect. BA1105 introduces amino acid mutations in the Fc region to enhance the ADCC effect. The mutations increase the affinity of the antibody to the agonistic Fc receptor CD16a without changing the affinity to the inhibitory receptor CD32b, preventing the tumor-killing efficacy of BA1105 from being inhibited by the inhibitory receptor CD32b.



The Fc-region in BA1105 inducts ADCC effect

Potential market opportunities and competition

According to the Frost & Sullivan Report, China incidence of gastric cancer increased from 429.0 thousand in 2017 to 483.9 thousand in 2021, with a CAGR of 3.1%, and it is expected to be 622.4 thousand in 2030, with a CAGR of 2.8% from 2021 to 2030. For patients with advanced metastatic gastric cancer, systemic treatment has been adopted clinically at present. Chemotherapy and targeted therapy are the main treatments for advanced metastatic gastric cancer. In the 2021 CSCO guideline, nivolumab in combination with FOLFOX/XELOX is class I recommendation for the first-line treatment of HER2-negative advanced gastric cancer (PD-L1 CPS≥5). Nivolumab is also class I recommendation for the third-line or subsequent treatment of HER2-positive/negative advanced metastatic gastric cancer. Judging from the existing treatment plans, it is difficult to effectively prolong the survival time of patients with advanced gastric cancer and new target therapy drugs are needed to improve the treatment effect.

According to the Frost & Sullivan Report, China incidence of esophageal cancer increased from 262.9 thousand in 2017 to 298.9 thousand in 2021 with a CAGR of 3.3%. Driven by the penetration of early screening and other factors, it is expected to further increase to 389.2 thousand in 2030, with a CAGR of 3.0% from 2021 to 2030. Chemotherapy and targeted therapy are the major treatments for advanced metastatic esophageal carcinoma and gastroesophageal junction carcinoma. In the 2021 CSCO guideline, nivolumab in combination with 5-FU/capecitabine and oxaliplatin is class II recommendation for the first-line treatment of advanced esophageal adenocarcinoma (CPS≥5). Nivolumab is also class II recommendation for second-line or subsequent treatment of advanced metastatic esophageal squamous cell carcinoma.

With the trend of aging population, increasing obesity and diabetes, as well as chronic liver disease, the incidence of pancreatic cancer in China grew rapidly in recent years. From 2017 to 2021, the incidence of pancreatic cancer in China has increased from 101.5 thousand to 115.9 thousand, representing a CAGR of 3.4%. The incidence will keep increasing and is estimated to reach 155.8 thousand in 2030, with a CAGR of 3.3% from 2021 to 2030. The treatment of pancreatic cancer mainly includes surgical treatment, radiotherapy, chemotherapy, interventional therapy, ERCP related treatment and TCM treatment. Currently, the option of targeted therapies is quite limited. Several targeted therapies besides erlotinib have been assessed in combination with gemcitabine, but none has shown to significantly impact outcomes.

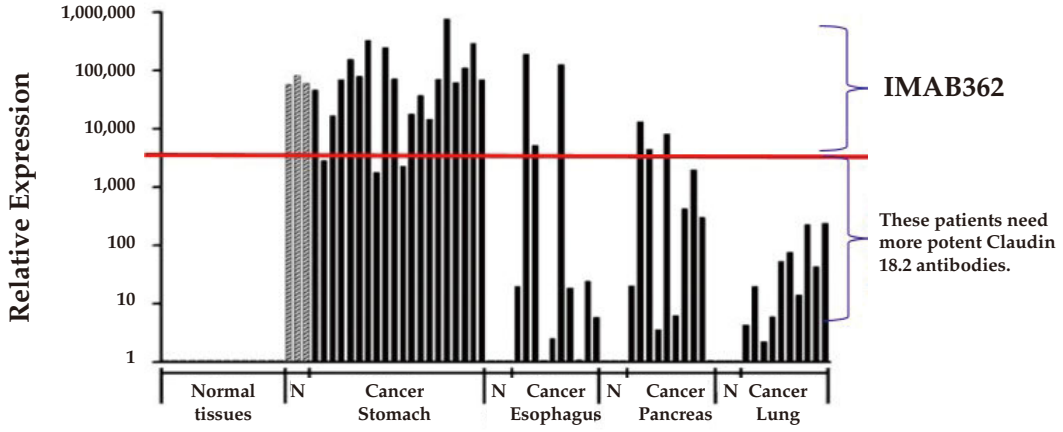
Claudin 18.2 is a potential target of gastrointestinal tumors and has good potential anti-tumor activity. As a transmembrane protein involved in the regulation of tight junctions between cells, Claudin 18.2 protein can be consistently and stably expressed in gastrointestinal tumors. For example, based on results from the FAST Phase 2 trial of IMAB362, 49% of patients with gastric, gastroesophageal junction, and esophageal cancers have positive Claudin 18.2 expression (≥2+ intensity in ≥40% of tumor cells). The development of therapeutic antibodies against Claudin 18.2 has high anticancer potential. Claudin 18.2 is also a potential target of pancreatic cancer. For example, in an in vitro feasibility study of IMAB362, 54.6% of samples of primary pancreatic ductal adenocarcinoma have shown high expression of Claudin 18.2 (with staining intensities of > 2+).

As of the Latest Practicable Date, several monoclonal antibodies, such as IMAB362 (zolbetuximab) developed by Astellas, were in the clinical research stage. As a monoclonal antibody with the same target, in its FAST Phase 2b study and evaluation of IMAB362 combined with EOX regimen (epirubicin, oxaliplatin combined with capecitabine) versus EOX regimen in the first-line treatment of Claudin 18.2 positive advanced gastric cancer and adenocarcinoma of the esophagogastric junction, it was found that the combined treatment group, as compared with the EOX group, significantly improved the PFS (7.5 m vs. 5.3 m, P<0.0005) and OS (13 m vs. 8.4 m, P=0.0008) in patients and that the superiority of IMAB362 was more obvious in patients with high Claudin 18.2 expression (OS: 16.7 m vs. 9.0 m), which significantly improved the clinical benefit of patients. For more details of the competitive landscape of Claudin 18.2-targeted therapies in China, please see "Industry Overview — Oncology biologics market — Oncology innovative drug market — Claudin 18.2 based antibody market — Competitive landscape".

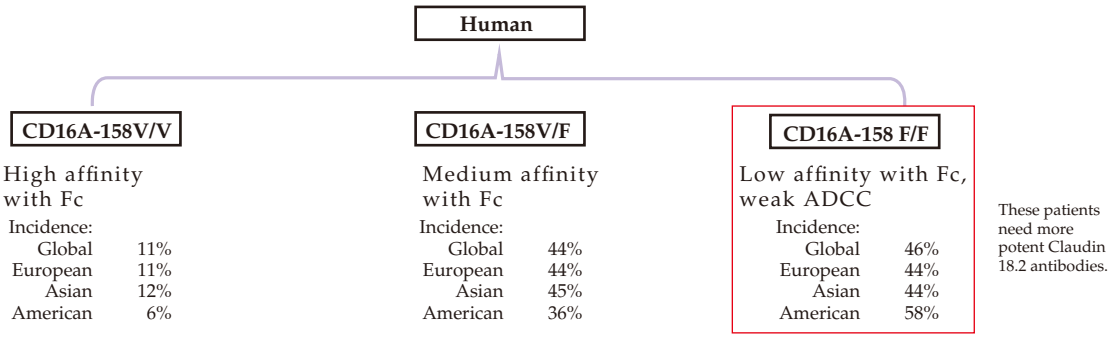
At the same time, with the Claudin 18.2 monoclonal antibody developed by a number of biopharmaceutical companies starting to be used in the clinical research of single drug or combined chemotherapy in the treatment of Claudin 18.2 positive advanced gastric cancer, and by reference to the current IMAB362 single drug or combined first-line chemotherapy regimen for the treatment of Claudin 18.2 positive patients with gastric cancer and adenocarcinoma of the esophagogastric junction, it is speculated that Claudin 18.2 monoclonal antibodies will have good potential antitumor activity and significant clinical advantages over existing treatments.

BA1105 is an ADCC-enhanced, fully human monoclonal antibody targeting Claudin 18.2. The *in vitro* pharmacodynamic results showed that compared with IMAB362, BA1105 had higher affinity, and on cell models with high or low expression of Claudin 18.2, and 158F/F or 158V/F genotypes had stronger ADCC effect. ADCC enhancement technology can improve the tumor-killing efficacy of BA1105 and is expected to have better therapeutic effects on patients with pancreatic cancer, gastroesophageal cancer, lung cancer and CD16A-158F/F genotype with low expression of Claudin 18.2. The following diagram sets forth the findings in more detail:

ADCC-enhanced version targeting patients with low expression of Claudin 18.2



ADCC-enhanced Version Targeting CD16A-158F/F Patients



Based on the above advantages, BA1105 project is expected to have a large market demand. We believe our BA1105 is a potential best-in-class drug candidate for the treatment of gastric cancer with Claudin 18.2 expression because it targets a larger applicable patients pool and demonstrates a more favorable safety profile compared to other drug candidates entering into clinical trials.

Summary of clinical development history and results

Clinical development

Ongoing Phase 1 clinical trial

Study design. The ongoing Phase 1 clinical trial is a multi-centered, open-label and single-agent study of BA1105 or combination chemotherapy, designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and preliminary efficacy of BA1105. The monotherapy phase will expand to patients with advanced solid tumors who have failed standard therapy. The enrolled patients are expected to be classified into six groups with each group applying the different dose i.e., 0.9 mg/kg, 2.7 mg/kg, 8 mg/kg, 16 mg/kg, 24 mg/kg and 32 mg/kg. The Bayesian Optimal Interval ("**BOIN**") design is used for the dose escalation, with the target toxicity rate of 0.3. The combination chemotherapy will be applied to patients with advanced gastric cancer and adenocarcinoma of the esophagogastric junction with high expression of Claudin 18.2, and the selection of dose escalation will be determined according to the results of monotherapy.

Safety, tolerability, PK, immunogenicity and preliminary efficacy. As of the Latest Practicable Date, the Phase 1 clinical trial for BA1105 remained ongoing, and thus its safety, tolerability, PK, immunogenicity and preliminary efficacy findings were not yet available.

Pre-clinical research

The pre-clinical results of BA1105 show that it can bind to human Claudin 18.2, C1q and Fc receptors from different species, and has strong binding activity to cells with low or high expression of Claudin 18.2. For a variety of different effector cells, BA1105 can induce strong ADCC activity. The *in vivo* efficacy showed that BA1105 alone or in combination with chemotherapy drugs showed strong anti-tumor activity in wild-type and Claudin 18.2 over-expressed nude mouse xenograft models, without any significant effect on the rat's nervous or respiratory system and the monkey's cardiovascular system. The single/repeated dose pharmacokinetic/toxicokinetic studies in rats and rhesus monkeys showed that the increase in exposure in each dose group is proportional to the dose increase, and there was no significant gender difference. ADA can be seen in some animals in the pharmacokinetic test. The toxicity studies with repeated administration to rats and rhesus monkeys showed that the main toxic target organ of BA1105 was the stomach.

Therefore, enhanced ADCC effect can improve the tumor-killing efficacy of BA1105, so this product has the potential to become the best targeted drug for the similar treatment of metastatic pancreatic cancer, advanced gastric cancer and adenocarcinoma of the esophagogastric junction.

Material communications and next steps

We received the IND approval for BA1105 from the NMPA in September 2021, and initiated the Phase 1 clinical trial in January 2022. We plan to complete the ongoing Phase 1 clinical trial in December 2023. Other than the above, we have not had any material regulatory communications with the NMPA or CDE for BA1105, and we are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA1105.

Collaboration arrangements and commercialization plans

We intend to manufacture BA1105, once approved, at our Yantai Site for distribution in China. See "— Manufacturing" in this section for further details on the technologies utilized in the Yantai Site. Our marketing efforts will primarily target hospitals across China leveraging our existing distribution network of Boyounuo® (BA1101). We will also explore the possibility of expanding the commercialization of BA1105 to overseas markets.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA1105.

BA1201

Overview

We are developing BA1201, which is an anti-PD-L1/TGF-β bifunctional fusion protein intended for the treatment of SCLC, NSCLC, cervical cancer, urothelial carcinoma, and advanced gastrointestinal tumors. We began the development of BA1201 in September 2019 and received the IND approval for BA1201 from the CDE in December 2021. In August 2022, we initiated the Phase 1 clinical trial in China. This drug candidate is our first novel bispecific antibody drug that has been approved to initiate clinical trial. Different from the monoclonal antibodies against a single target, bispecific antibodies can bind to two targets at the same time and regulate two signaling pathways related to the treatment of cancer, which has unique advantages in cancer immunotherapy. BA1201 includes an anti-PD-L1 antibody infused with TGF-β Type II Receptor domain at its C terminal. BA1201 can not only inhibit PD-L1/PD-1 signaling pathway but also inhibit TGF-β/TGF-β RII signaling pathway, which can eliminate immunosuppression and restore the immune system to target tumor cells for killing, making it more potent than anti-PD-L1 monoclonal antibodies.

Mechanism of action

BA1201 is an anti-PD-L1/TGF-β bifunctional fusion protein that may simultaneously target PD-L1 and transforming growth factor-β ("**TGF-β**"). The combination of anti-PD-L1 monoclonal antibody and TGF-β RII may simultaneously block the two signaling pathways mediated by PD-L1 and TGF-β, thus immune response against tumors is enhanced to inhibit tumor growth.

PD-L1 is an important immune inhibitory regulator that mediates tumor immune escape. Tumor cells bind PD-1 molecules on T cells through PD-L1 molecules on their cell surface, which inhibits the anti-tumor immune responses such as the proliferation and activation of T lymphocytes and the production of cytokines. PD-L1 may also bind to B7.1 on T cells and antigen-presenting cells, which downregulates immune response, inhibits T cell proliferation and activation and promotes tumor cell immune escape. The antitumor effect of T cell may be recovered if the interaction between PD-L1 and PD-1 or B7.1 is blocked. TGF-β may regulate tumor cell growth and differentiation through multiple aspects, such as promoting the proliferation of Treg and other immunosuppressive cells, mediating the formation of tumor immunosuppressive microenvironment and accelerating tumor progression, which is one of the mechanisms leading to anti-PD-L1 resistance. Therefore, blocking the PD-1/PD-L1 and TGF-β/TGF-β RII signaling pathways together would restore the anti-tumor immune ability of tumor-specific T cells, reverse the tumor immunosuppressive microenvironment, overcome the resistance to anti-PD-L1 antibody and thus improve the anti-tumor effects.

Potential market opportunities and competition

Immuno-oncology has attracted much attention in recent years, and it is the focus of the field of tumor treatment. Immuno-oncology therapy is designed to stimulate the patient's own immune system to generate or enhance an antitumor immune response in order to control or clear cancer cells. Due to its ability to provide durable remissions while being generally well-tolerated in certain patients with advanced cancers, the discovery and development of immuno-oncology therapy in recent years mark a milestone in cancer treatment. Immuno-Oncology therapies are emerging cancer therapies in global market, including the therapies of cytokines, therapeutic cancer vaccine, checkpoint monoclonal antibodies and adoptive cell transfer therapies. The global immune-oncology therapies market increased from US$14.1 billion in 2017 to US$42.6 billion in 2021, with a CAGR of 31.9%, and is expected to increase to US$216.6 billion in 2030, with a CAGR of 19.8% from 2021 to 2030. Similarly, the China immune-oncology therapies market increased from RMB0.9 billion in 2017 to RMB16.3 billion in 2021, with a CAGR of 108.2%, and is expected to increase to RMB256.4 billion in 2030, with a CAGR of 35.8% from 2021 to 2030.

BA1201 is a PD-L1/TGF-β bifunctional fusion protein in the therapeutic area of immune-oncology, targeting PD-L1 and TGF-β, with a broad spectrum, and also possesses a number of clear advantages. The PD-L1/TGF-β bifunctional fusion antibody is the second-generation and more potent PD-1/PD-L1 antibody. The clinical trials with existing results have shown a clear curative effect and a broad spectrum of indications. For example, the PD-L1/TGF-β bifunctional fusion protein M7824 developed by Merck has been used simultaneously in clinical researches on several types of solid tumors. The FDA has granted orphan drug designation to the indication for cholangiocarcinoma. Therefore, we believe that there are clinical demands and great development opportunities for the PD-L1/TGF-β bifunctional fusion protein.

As of the Latest Practicable Date, there were 15 product candidates with the same target in China which have entered the clinical trial stage. M7824 developed by Merck and SHR-1701 developed by Jiangsu Hengrui Medicine were at the forefront and had entered Phase 3 clinical trials. Both of them have shown certain curative effects in cervical cancer, NSCLC and other indications, and are currently in the exploratory stage. For more details, see "Industry Overview — Oncology biologics market — Oncology innovative drug market — PD-L1/TGF-β market — Competitive landscape".

The existing basic and clinical studies have shown that PD-L1/TGF-β bifunctional fusion proteins have important therapeutic value for advanced tumors. PD-L1/TGF-β bifunctional inhibitors achieve anti-tumor effects by antagonizing both PD-L1 and TGF-β signaling pathways. PD-L1/TGF-β bifunctional inhibitors may activate the endogenous and exogenous immune systems at the same time, achieve dual anti-tumor effects, and antagonize the creation of an inhibitory immune microenvironment. The existing clinical data shows that M7824 has good clinical results in various refractory tumors such as human HPV virus-related cancer, biliary tract cancer, and gastric cancer.

As shown by the existing basic and pre-clinical studies, BA1201 has a high affinity for PD-L1 and TGF-β *in vitro*, and may effectively bind to TGF-β1, TGF-β3 and PD-L1; and it has good antitumor efficacy *in vivo*. The anti-tumor effect of this product is better than that of PD-L1 antibody and TGF-β RII antibody alone. Compared with similar competing products, BA1201 has better binding sensitivity on PD-L1 positive cells, and its IC_{50} (semi-inhibitory concentration) is three times lower; it has good stability and long half-life in mice and cynomolgus monkeys, and has a low risk of cardiotoxicity. Thus, BA1201 has favorable PD profile and acceptable safety risk.

Summary of clinical development history and results

Clinical development

Ongoing Phase 1 clinical trial

Study design. The Phase 1 clinical trial is a multi-centered, non-randomized, open-label and dose-escalation study on patients with advanced solid tumors. Part A: A single-agent dose escalation study on advanced solid tumors consists of the 21-day dose limiting toxicity ("**DLT**") observation period and subsequently the Q2W multiple-dose treatment period. Part B: Based on the data gradually obtained from Part A, we determine the potential indications, and simultaneously seek different doses and administration frequencies based on different indications. We may provide administration once every two weeks or three weeks to the subjects.

As of the Latest Practicable Date, the Phase 1 clinical trial for BA1201 remained ongoing, and thus the findings were not yet available.

Pre-clinical research

The results of pre-clinical studies showed that BA1201 had a high affinity and significant anti-tumor activity in several mouse models. Compared with benchmark, BA1201 had a better binding sensitivity on PD-L1 positive cells (with a three times lower IC_{50}). It had a good stability and longer half-life in mice and cynomolgus monkeys, and had a low risk for cardiotoxicity.

Material communications and next steps

We received the IND approval for BA1201 from the CDE in December 2021. We plan to complete the Phase 1 clinical trial in December 2023. Other than the above, we have not had any material regulatory communications with the NMPA or CDE for BA1201, and we are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA1201.

Collaboration arrangements and commercialization plans

We intend to manufacture BA1201, once approved, at our Yantai Site for distribution in China. See "— Manufacturing" in this section for further details on the technologies utilized in the Yantai Site. Our marketing efforts will primarily target hospitals across China leveraging our existing distribution network of Boyounuo® (BA1101). We will also explore the possibility of expanding the commercialization of BA1201 to overseas markets.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA1201.

BA-CovMab

Overview

We are developing BA-CovMab, a fully human monoclonal antibody manufactured by recombinant technology and used to counteract COVID-19. We began developing BA-CovMab in April 2022 and have been conducting the Phase 1 clinical trial in China since October 2022. Based on our preliminary clinical findings, BA-CovMab could be a SARS-CoV-2 neutralizing antibody candidate against SARS-CoV-2. We plan to launch BA-CovMab initially in China after we receive regulatory approval and may also explore the possibility of expanding the commercialization of BA-CovMab to other overseas markets. An *in vitro* pseudovirus-based neutralization assay showed that BA-CovMab could effectively neutralize 18 SARS-CoV-2 variants, and the IC50 values for Omicron BA.1, BA.2, BA.2.12.1, BA.2.13, BA.2.75, BA.3, BA.4 and BA.5 were 1.24-5.52 ng/mL.

Since the COVID-19 outbreak, a variety of mutant strains such as Alpha, Beta, Delta, and Omicron have appeared around the world. The continuous mutation of the virus has strengthened its infectivity and escape ability, affecting the protection of vaccines and the efficacy of therapeutic drugs. We hope that BA-CovMab can broadly neutralize current and possible future variants. However, the SARS-CoV-2 B.1.1.529 (Omicron) variant contains 15 mutations of the receptor-binding domain (RBD) and might evade RBD-targeted neutralizing antibodies according to the article "Omicron escapes the majority of existing SARS-CoV-2 neutralizing antibodies" published in Nature authored by Cao, Y., Wang, J., Jian, F. et al in 2022. For more details, see "Risk Factors — Risks relating to the commercialization of our drug candidates — We may not be able to successfully commercialize LY-CovMab, one of our Core Products, or BA-CovMab, which may negatively affect our business, results of operations and business prospects".

Mechanism of action

BA-CovMab is a recombinant human monoclonal neutralizing antibody identified through the sequential immunization and sequential screening with the Spike ectodomain proteins or Receptor-Binding Domain (RBD) proteins from multiple SARS-CoV-2 variants. The antibody can specifically bind to the RBD in Spike proteins and effectively block the virus from binding to the host cell's ACE2 receptor, thereby preventing the SARS-CoV-2 virus from entering the host cells. Cryo-electron microscopy studies show that BA-CovMab avoids most mutation-sensitive sites in the RBD of SARS-CoV-2 spike protein and can broadly and effectively neutralize diverse SARS-CoV-2 variants with a lower risk for loss of neutralizing activity against future variants.

Potential market opportunities and competition

As the pathogen of COVID-19, SARS-CoV-2 is continuing to spread and cause the global pandemic with millions of confirmed COVID-19 cases including over 6.0 million deaths as of the Latest Practicable Date according to the data of the WHO. Patients are still facing few options for effective medications. See "Our innovative antibody portfolio — Our Core Product: LY-CovMab — Potential market opportunities and competition" in this section for more details.

The COVID-19 pandemic has lasted for more than two years. Although countries around the world have carried out large-scale vaccination and a variety of therapeutic drugs have been put into use, the continuous mutation of the virus has weakened the protective efficacy and drug efficacy of previous vaccines, and the infection rate remains high. In the future, the COVID-19 will become a persistent infectious disease, and the development of new drugs is still necessary. Generally, neutralizing antibodies target the S (spike) protein and block receptor binding or membrane fusion, thereby preventing viral entry into host cells. Therefore, COVID-19 neutralizing antibodies have potential in both preventive or therapeutic uses.

According to Frost & Sullivan, drug development for infectious diseases generally involves the concurrent development of multiple drug candidates at different targets. As an infectious disease, COVID-19 continues to have different mutations. Because the direction of the mutation in the future cannot be predicted, we are developing LY-CovMab and BA-CovMab for different targets. LY-CovMab is mainly aimed at Alpha, Delta, Gamma, Lambda and future potential isotopic variants generated in the early stage of the COVID-19 outbreak. BA-CovMab neutralized 18 variants including Omicron BA.1-BA.5. Because COVID-19 continues to have different mutations and LY-CovMab and BA-CovMab each deals with different variants of COVID-19, the two product candidates are complementary rather than competing with each other. Therefore, the commercialization of LY-CovMab will not cannibalize the development of BA-CovMab.

Summary of clinical development history and results

Clinical development

Ongoing Phase 1 clinical trial

Study design. The Phase 1 clinical trial is a first-in-human (FIH) single-dose ascending (SAD) clinical study to evaluate the safety, tolerability, pharmacokinetic profile, and immunogenicity of a single dose of BA-CovMab Injection in healthy subjects in China.

As of the Latest Practicable Date, the Phase 1 clinical trial for BA-CovMab remained ongoing, and thus the findings were not yet available.

Pre-clinical research

Based on the results of preclinical pharmacodynamic studies, there were several findings: (i) an in vitro pseudovirus-based neutralization assay showed that BA-CovMab could effectively neutralize 18 SARS-CoV-2 variants, and the IC50 values for Omicron BA.1, BA.2, BA.2.12.1, BA.2.13, BA.2.75, BA.3, BA.4 and BA.5 were 1.24-5.52 ng/mL; (ii) an *in vitro* authentic-based neutralization assay showed that BA-CovMab was excellent in neutralizing Omicron BA.1 and BA.2, with the IC50 values as 53.20 ng/mL and 18.17 ng/mL respectively; (iii) BA-CovMab had high affinity to the RBD proteins of nine SARS-CoV-2 variants, including the wild-type (WT) strain, B.1.1.7, B.1.351, P.1, B.1.617.2, as well as Omicron B.1.1.529, C.37, B.1.621 and B.1.617.1, and maintained high blocking activity against eight out of nine SARS-CoV-2 variants tested apart from B.1.621; and (iv) an efficacy study against authentic viruses in mice showed that BA-CovMab could effectively prevent and treat infection by Omicron BA.1 and BA.2, as it significantly reduced lung virus titers by 2 and 3.5 log10 ($p<0.005$) in two infected animal models, respectively, indicating that the viruses were basically eliminated from the lung and the antibody provided excellent protection.

Material communications and next steps

We received the IND approval for BA-CovMab from the CDE in September 2022. When we submitted the IND application, we submitted the neutralization activity data of the 18 variants including Omicron BA.1-BA.5. The CDE recommended that we continue to track the mutation of the new coronavirus, and conduct corresponding neutralization activity studies when necessary according to the prevalence of the mutant strains. We plan to complete the Phase 1 clinical trial in the second quarter of 2023 and initiate the Phase 2 clinical trial in the second half of 2023. Other than the above, we have not had any material regulatory communications with the NMPA or CDE for BA-CovMab, and we are not aware of any material concern from the NMPA or the CDE in connection with our ongoing development of BA-CovMab.

Collaboration arrangements and commercialization plans

After we successfully obtain regulatory approval for BA-CovMab, we intend to begin commercial manufacturing of BA-CovMab for distribution initially in China. We may utilize our dedicated in-house sales and marketing team and cooperate with business partners including promoters and distributors to commercialize BA-CovMab in China. We will develop a detailed business plan for BA-CovMab after the completion of Phase 2 clinical trial, and explore business cooperation opportunities in China and overseas based on Phase 2 clinical results.

WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND COMMERCIALIZING BA-CovMab.

Other innovative antibody candidates

Our other innovative antibody candidates are in pre-clinical studies or in the preparation of clinical trials which include:

- BA1106. BA1106 is an innovative CD25 fully human monoclonal antibody independently developed by us. CD25 is also known as interleukin-2 receptor alpha ("**IL-2Ra**"). It is expressed at high levels on Treg, and does not exist or is expressed at low levels on effector T cells. It is one of the potential molecular targets to achieve Tregs depletion. The main mechanism of action of BA1106 is to kill Treg cells in the tumor microenvironment through ADCC effector function and increase the proportion of effector T cells. CD25 antibody is a broad-spectrum immuno-oncology drug, with potential indications for cervical cancer, renal cancer, ovarian cancer, melanoma, pancreatic cancer, hepatocellular carcinoma, gastric cancer and breast cancer.

  The competing product candidate with the same target is RG6292, a new anti-CD25 antibody under development by Roche. Roche has registered two Phase I clinical trials for this antibody. Except for RG6292, there are currently no other reported anti-CD25 antibodies under development in the anti-tumor field. BA1106 has the characteristics of strong antibody targeting, mainly depleting Tregs inside solid tumors, and may use autoimmune T cells to kill tumor cells without affecting the normal IL-2 signaling pathway. In addition, BA1106 is compatible with immune checkpoint inhibitors, such as PD-1/PD-L1 antibody, and has a synergistic effect and a broad-spectrum anti-tumor effect. Therefore, we believe that BA1106 has a potential good market prospect. See "Industry Overview — Oncology biologics market — Oncology innovative drug market — CD25 market — Competitive landscape" for more details of the competitive landscape of BA1106.

In November 2021, we published the related research results of BA1106 in *Scientific Reports*, a sub-issue of *Nature* magazine. In September 2022, we have received the IND approval for BA1106. This makes BA1106 the first investigational anti-CD25 antibody to start clinical trials in China for treating solid tumors. As of the Latest Practicable date, we were preparing for the Phase 1 clinical trial of BA1106 in China, and we plan to initiate the Phase 1 clinical trial in China in the first quarter of 2023.

- BA1202. BA1202 is a bispecific antibody targeting CEA and CD3 developed by us through the bispecific T-cell engager technology platform. It adopts a novel butterfly antibody structure which retains the Fc region and may connect with CD3 on the T cell receptor ("**TCR**") complex and CEA expressed on tumor cells and then activate endogenous T cells to eliminate CEA-positive tumor cells. It is mainly used to treat solid tumors including advanced mCRC, pancreatic duct adenocarcinoma and other CEA-positive tumors.

  As a bispecific antibody molecule, BA1202 connects with CD3 on T cells and connects with CEA on tumor cells resulting in the direct killing effect of T cells against tumor cells. By reducing CD3 affinity, we may significantly reduce CRS without affecting the killing effect on target cells. CEA/CD3 bispecific antibody has synergistic effect with immunosuppressants PD-1 (Opdivo®) and PD-L1 (Atezolizumab), and such synergistic effect increases with the infiltration of T cells into tumors.

  Many patients with advanced colorectal cancer are still in generally good condition after standard first- and second-line chemotherapy plus targeted drug therapy. They need more treatments to extend the lifespan or control symptoms, but there are limited options for third-line therapies. The great clinical demands have not been satisfied. BA1202 has shown a good effect of completely inhibiting tumors in a mouse with colorectal cancer, and simultaneously shown a significant dose-related effect. There was a tumor-inhibiting effect at 0.1 mg/kg. Compared with comparable CEA/CD3 antibody drugs under research, BA1202 shows stronger *in vitro* activity and *in vivo* efficacy. The successful development of BA1202 will provide new treatment options to patients with colorectal cancer and pancreatic cancer. See "Industry Overview — Oncology biologics market — Oncology innovative drug market — CEA/CD3 market — Competitive landscape" for more details of the competitive landscape of BA1202.

  We were conducting the pre-clinical process research of BA1202 as of the Latest Practicable Date, and we plan to submit the IND application in the first half of 2023.

- BA1301. BA1301 is an anti-Claudin 18.2 ADC independently developed by us. It uses the targeting characteristics of antibodies to improve the selectivity and specificity of small molecule drugs (Duo-5 (Duostatin-5, auristatin derivative)) against tumor tissue, as a result of jointly exerting anti-tumor effect, and also may reduce the toxic and side effects of small molecule drugs on normal tissues. BA1301 is a freeze-dried agent, which is administered by intravenous drip. It is mainly used to treat gastric cancer, esophageal cancer and pancreatic cancer.

  Claudin 18.2 is highly expressed mainly in digestive system tumors and their metastases. It has the characteristics of high selectivity, stable expression in specific tumor tissues, and participation in the proliferation, differentiation and migration of tumor cells. It has the potential for diagnosis and treatment in gastric cancer, pancreatic cancer, esophageal cancer and other types of tumors. At present, domestic pharmaceutical companies have conducted many new attempts in the R&D competition for Claudin 18.2 target, including bispecific antibodies, CAR-T, ADC drugs, etc.

  Compared with monoclonal antibodies, BA1301 has higher efficacy in theory because it can release highly active cytotoxins in tumor tissue. Compared with chemotherapy drugs, BA1301 has the targeting characteristics of antibodies, which may greatly improve the selectivity and specificity of small molecule drugs against tumor tissue and reduce significantly the toxic and side effects of small molecule drugs on normal tissues. See "Industry Overview — Oncology biologics market — Oncology innovative drug market — Claudin 18.2 based antibody market — Competitive landscape" for more details of the competitive landscape of BA1301.

  According to pre-clinical study results, BA1301 has shown significant efficacy in a mouse with gastric cancer and has low non-specific killing of negative cells. We submitted the IND application in October 2022.

- BA2101. BA2101 is an IL4R long-acting molecular antibody independently developed by us. It may block IL-4 and IL-13 signaling pathways at the same time, regulate type 2 immunity, reduce the content of eosinophils and IgE, and treat allergic diseases caused by Th2 type immunity. It is mainly used to treat atopic dermatitis, asthma, sinusitis, pruritus and urticaria, and the mode of administration is subcutaneous injection.

Immunization and respiration is a fast-growing market, and the deployment therein is conducive to seizing the opportunity for the next wave of growth in the pharmaceutical market. Globally, dupixent (dupilumab) became the first targeted biologic approved for the treatment of moderate-to-severe atopic dermatitis in the U.S. in March 2017 and in Europe in September 2017, and is so far the only targeted biologic for the treatment. Dupixent was also approved for the treatment of moderate-to-severe asthma in the U.S. in October 2018 and approved for the treatment of severe asthma in Europe in March 2019.

Compared with the bi-weekly dosing cycle of Dupixent, BA2101 as a long-acting molecule may achieve a dosing cycle of at least once a month. The IL-4R antibody has the similar efficacy to Dupixent in the mouse asthma model, and has a longer half-life in cynomolgus monkeys. BA2101 does not cross react with the monkey IL-4R. It will have extensive marketing prospects in atopic dermatitis, asthma, nasal polyposis, urticaria, and chronic obstructive pulmonary disease ("**COPD**"), and is expected to become the most important drug for autoimmune diseases in the future. See "Industry Overview — Autoimmune innovative drug market — IL4R market — Competitive landscape" for more details of the competitive landscape of BA2101.

In August 2022, we submitted the IND application for BA2101 and received the IND approval in October 2022. We plan to initiate the Phase 1 clinical trial in China in the first quarter of 2023.

INTELLECTUAL PROPERTY

As a biopharmaceutical company, we are keenly aware of the importance of establishing and protecting our intellectual property rights. We have filed a number of patent applications for our drug candidates in various jurisdictions, and expect to rely on a combination of patents, trademarks, trade secrets and other intellectual property rights, as well as employee and third-party confidentiality agreements, in order to safeguard our intellectual properties.

As of the Latest Practicable Date, we had 25 granted patents and 44 pending patent applications worldwide. The following table sets forth the portfolio of material patents and patent applications as of the Latest Practicable Date:

Drugs, drug candidates or platforms	Title	Type	Patent applicant/ holder	Jurisdiction of registration	Patent number/ application number	Status	Date of application	Expected expiry date if granted[1]
LY-CovMab	Neutralizing antibody of SARS-CoV-2 virus and application thereof (SARS-CoV-2病毒的中和抗體及其應用)	Invention	Our Company	PCT	PCT/CN2021/098077	Pending	June 3, 2021	N/A

Drugs, drug candidates or platforms	Title	Type	Patent applicant/ holder	Jurisdiction of registration	Patent number/ application number	Status	Date of application	Expected expiry date if granted[1]
LY-CovMab	A method to treat or prevent the disease caused by the new coronavirus SARS-CoV-2 (一種治療或預防新型冠狀病毒SARS-CoV-2引起的疾病的方法)	Invention	Our Company	PCT	PCT/CN2021/121556	Pending	September 29, 2021	N/A
LY-CovMab	Neutralizing antibody of SARS-CoV-2 virus and application thereof (SARS-CoV-2病毒的中和抗體及其應用)	Invention	Our Company	PRC	ZL202180003751.7	Granted	June 3, 2021	June 3, 2041
Boyounuo® (BA1101)	Purification of protein by cation exchange chromatography (利用陽離子交換層析純化蛋白質)	Invention	Our Company	PRC	ZL201410359482.X	Granted	July 25, 2014	July 25, 2034
BA1102	A 2000L-scale cell culture method for producing monoclonal antibodies (一種2000L規模細胞培養生產單抗的方法)	Invention	Our Company	PRC	CN202111114231.1	Pending	September 23, 2021	N/A
BA6101	A 500L-scale cell culture method for producing monoclonal antibodies (一種500L規模細胞培養生產單抗的方法)	Invention	Our Company	PRC	CN202111106580.9	Pending	September 22, 2021	N/A
BA9101	A purification method of VEGF capture agent fusion protein (VEGF捕獲劑融合蛋白的純化方法)	Invention	Our Company	PRC	ZL201711346802.8	Granted	December 15, 2017	December 15, 2037

Drugs, drug candidates or platforms	Title	Type	Patent applicant/ holder	Jurisdiction of registration	Patent number/ application number	Status	Date of application	Expected expiry date if granted[1]
BA9101	A purification method of recombinant fusion protein by linear elution (採用線性洗脫步驟的重組融合蛋白純化方法)	Invention	Our Company	PRC	ZL201711351111.7	Granted	December 15, 2017	December 15, 2037
Human Antibody Transgenic Mouse platform	A preparation method of transgenic animal expressing human antibody (一種能夠表達人抗體的轉基因動物的製備方法)	Invention	Our Company	PRC	ZL201210281415.1	Granted	August 9, 2012	August 9, 2032
Bispecific T-cell engager technology platform	Optimized anti-CD3 arm in the generation of T-cell bispecific antibodies for immunotherapy	Invention	Our Company	PCT	PCT/CN2020/136452	Pending	December 15, 2020	N/A

Note:

(1) Patent expiration does not include any applicable patent term extensions.

We are of the view that there is no material legal impediment for us to obtain the approvals for all of our pending patent applications, subject to the examination opinions from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications. Specifically, our legal advisors have checked and reviewed the legal status of our pending patent applications in relation to the Core Products in the public online databases of the China National Intellectual Property Administration (CNIPA), World Intellectual Property Organization (WIPO) and some other public patent databases as well as the information provided by us regarding the patent applications. Our legal advisors are not aware of any fact or legal impediment with respect to those pending patent applications that would preclude the issuance of patents with respect to such applications except that these patent applications remain subject to the examination opinions from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications. We are of the view, after having consulted our legal advisors, that we have been granted patents or applied for patent applications that cover material patentable features relating to our Core Products and Commercialized Product in each planned jurisdictions where relevant patents and/or patent applications have been obtained/filed. Nevertheless, if we are unable to obtain and maintain patents in respect of any of our current and future patent applications and other intellectual property protection for our products, drug candidates and other technologies, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our drugs and technology

may be adversely affected, which in turn could have a material adverse effect on our business, financial condition and results of operations. Please refer to "Risk Factors — Risks relating to intellectual property — A portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents, and if our pending patent applications fail to receive approval, our business will be adversely affected. If we are unable to obtain, maintain and adequately protect our intellectual property rights, our business could suffer." for further details.

Our legal advisors are of the view that BA1102 and BA6101 are biosimilar products of drugs Xgeva® and Prolia® originally developed and patented by Amgen. Amgen owns a Chinese patent (ZL201310052370.5) covering the amino acid sequences of BA1102 and BA6101, which has expired since June 25, 2022. Amgen also owns a Chinese patent (ZL201310463795.5) covering the medical use of the OPG binding protein antagonist in reducing bone resorption in the mammal, which has expired since April 15, 2018. Therefore, these two patents will not affect the Company's rights to commercialize BA1102 and BA6101 in China at the contemplated timeframe. The Company filed Chinese patent applications directed to methods for producing the antibodies (CN202111106580.9 and CN202111114231.1) which may cover the methods for producing BA1102 and BA6101. These two Chinese patent applications have not been granted yet. These patent applications, if granted, will block others from using the patented methods to develop the antibodies of BA1102 and BA6101 but others may still develop the antibodies using other methods. Therefore, the Company does not completely rely on the exclusivity provided by the grant of these patents in gaining its competitive advantages.

Our legal advisors are of the view that, LY-CovMab is originally developed by the Company. The Company has filed two PCT patent applications relating to LY-CovMab: i.e. PCT/CN2021/098077 and PCT/CN2021/121556. The PCT patent application PCT/CN2021/098077 has entered into Chinese national phase on January 6, 2022 and the Chinese patent application has been granted a patent right on June 21, 2022, with a patent number of ZL202180003751.7. The Chinese patent ZL202180003751.7 includes claims directed to many aspects of LY-CovMab, including the amino acid sequences of CDRs, heavy chain variable region and light chain variable region, and constant region, as well as nucleic acids, host cells, pharmaceutical compositions, kits and use of the claimed antibodies, nucleic acids or pharmaceutical compositions in preventing, treating, detecting or diagnosing diseases associated with SARS-CoV-2. The PCT patent application PCT/CN2021/098077 is still within the time period (until about December 4, 2022) for filing national patent applications in other countries and regions. The PCT patent application PCT/CN2021/121556 includes claims directed to uses of LY-CovMab for treating or preventing diseases associated with SARS-CoV-2 virus, and uses of pharmaceutical compositions comprising the antibodies. This PCT application is still within the time period (until about March 29, 2023) for filing corresponding patent applications in other countries and regions. In summary, the core patent that covers the sequences of LY-CovMab has been granted in China. This Chinese patent ZL202180003751.7 will preclude others from commercializing the antibody that comprises the same sequences as LY-CovMab in China during its patent term. But for other countries

or regions, there is no patent protection that could exclude others from commercializing the antibody that comprises the same sequences as LY-CovMab as of the Latest Practicable Date. The Company confirmed it does not plan to commercialize LY-CovMab in other countries or regions outside of China.

We also seek to protect our proprietary technology and processes by entering into confidentiality agreements with consultants, business partners and contractors. We have entered into confidentiality agreements and non-competition agreements with our senior management and certain core members of our research and development team and other key employees who have access to trade secrets or confidential proprietary information. Our standard employment contract contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of an employee's employment with us. However, despite measures taken to protect our intellectual property rights, third parties may nevertheless gain unauthorized access to our confidential information and trade secrets. See "Risk Factors — Risks relating to intellectual property" for further details.

Based on the FTO analysis of our Core Products, we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize our Core Products in China at the contemplated timeframe. Based on the FTO analysis of BA1102 and BA6101, we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize BA1102 and BA6101 in the United States and the EU at the contemplated timeframe. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to determine whether any existing patents cover a company's products, and whether making, using, offering to sell, or selling the products would infringe any existing patents. However, we cannot provide any assurance that all relevant third party patents were identified or that conflicting patents will not be issued in the future. For more information, see "Risk Factors — Risks relating to intellectual property".

As of the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceedings or claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent. Based on the review of public information, our PRC Legal Adviser did not find that we infringed on or misappropriated third parties' intellectual property rights during the Track Record Period and up to the Latest Practicable Date. Our Directors confirmed that we did not infringe on or misappropriate third parties' intellectual property rights, and we were not aware of any legal, arbitral or administrative proceedings of potential or confirmed infringement or misappropriation of any third parties' intellectual property rights by us, during the Track Record Period and up to the Latest Practicable Date. For further details, see "Statutory and General Information — B. Further information about our business — 2. Intellectual property rights of our Group" in Appendix VI to this document.

RESEARCH AND DEVELOPMENT

Overview

We boast our integrated biopharmaceutical platform, through which we have excelled in the discovery, development, manufacture and commercialization of antibody drugs with a focus on therapeutic areas of oncology, metabolism, autoimmunity and ophthalmology. We have accumulated substantial experience and know-how across all stages of antibody research and development, which enables us to efficiently develop antibody products from candidate generation to late-phase GMP manufacturing. As of the Latest Practicable Date, we had a total of 13 drug candidates, 10 of which had entered or completed clinical trials or received the IND approvals from the CDE. Since the incorporation of the Group, we had a total of 21 employees covering biopharmaceutical discovery research, biotechnology research, biopharmaceutical analysis research and pilot process research under the R&D team led by Dr. Dou Changlin, most of whom still remained in the R&D team as of the Latest Practicable Date. After approximately ten years' development, our R&D team primarily operates as project management teams consisting of 253 experienced employees from different teams, including 30 staff in the biopharmaceutical discovery research team, 53 staff in the biotechnology research team, 29 staff in the biopharmaceutical analysis research team, 14 staff in the biological activity research team, two staff in the non-clinical research team, 77 staff in the pilot process research team, 35 staff in the clinical research team, 13 staff in the regulatory affairs, project management and intellectual property team as of June 30, 2022. Dr. Dou Changlin, the president of R&D, oversees all pipeline product development including the pre-clinical studies and clinical trials of each of our Core Products and Commercialized Product since our incorporation. Dr. Dou is the key personnel responsible for the R&D for each of the Core Products and the Commercialized Product. The other key R&D members, also as key members of project management teams responsible for the development of our Core Products and Commercialized Product include Mr. Lu Jun (our senior vice president and head of biotechnology engineering center and quality department), Mr. Song Deyong (in charge of biopharmaceutical discovery research team), Mr. Shen Zhenduo (in charge of biopharmaceutical analysis research team) and Mr. Sun Baiping (in charge of biological activity research team), all of whom have remained with us since the discovery of the Core Products and the Commercialized Product, including their pre-clinical studies and clinical trials. See "Directors, Supervisors and Senior Management" for further details of Dr. Dou Changlin, Mr. Lu Jun and Mr. Song Deyong. Mr. Shen Zhenduo and Mr. Sun Baiping has more than 13 years and 11 years of experience in the biopharmaceutical industry, respectively, and they both joined our Company in March 2014 and served in successive roles in our biopharmaceutical analysis research team and biological activity research team, respectively. As of the Latest Practicable Date, the core R&D members of each of the Core Products have remained the same since commencing their development stages. As of June 30, 2022, our R&D team had 250 employees in China and three employees in Boston in the United States, most of whom had R&D and clinical experience of more than six years. Our experienced clinical development team is in charge of formulating clinical strategies and designing appropriate clinical trials to efficiently and expeditiously move forward R&D programs.

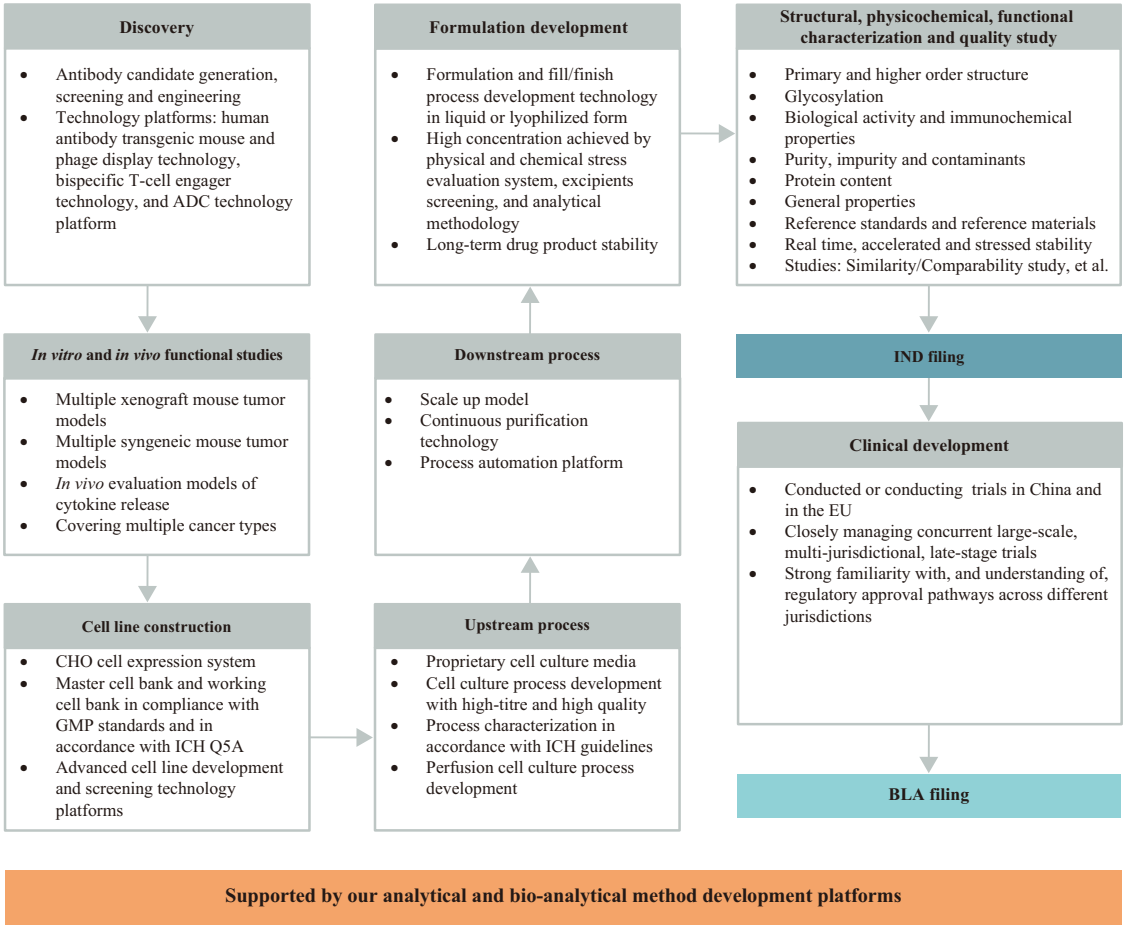
In order to bring forward the development of our pipeline products, by 2022 and 2023, we plan to expand our R&D team to add three and five staff, respectively, in the

biopharmaceutical discovery research team, 13 and 14 staff, respectively, in the biotechnology research team, five and 11 staff, respectively, in the biopharmaceutical analysis research team, three and three staff, respectively, in the biological activity research team, two and four staff, respectively, in the non-clinical research team, more than 50 and more than 30 staff, respectively, in the pilot process research team, more than 10 and more than 30 staff, respectively, in the clinical research team as well as three and two staff, respectively, in the regulatory affairs, project management and intellectual property team.

We are one of the few biopharmaceutical companies in China capable of executing R&D throughout the whole product development process, from early candidate generation to eventual BLA filing and commercialization. We have independently developed all of our drug candidates in-house, with proprietary know-how across the entire process. We have a fully-fledged proprietary R&D technology platform focusing on antibody discovery and drug development. We have R&D teams and facilities located in Yantai and Nanjing in China, with rich experience and strong performance track record in drug discovery and development, including having developed extensive experience in areas of antibody discovery, cell line development, upstream and downstream process development, analytical development, technology transfer, pilot and commercial scale production.

Our R&D team in Boston in the United States is mainly responsible for the research and development of the bispecific T-cell engager technology platform and relevant drug candidates under the development with the platform, as well as the research and development and cooperation of early frontier projects. For example, we are developing BA1202 in Boston, which is a bispecific antibody targeting CEA and CD3 developed through the bispecific T-cell engager technology platform. Each of our core management members in our R&D teams has more than ten years of experience in the pharmaceutical industry and some of them have overseas work experience in reputable pharmaceutical companies, such as Regeneron Pharmaceuticals, Inc., Genentech, Invitrogen Corporation, Cellular Dynamics International, A-Bio Pharma Pte, Eli Lilly, Ipsen Bioscience, Inc., Momenta Pharmaceutical Inc., etc. Dr. Dou Changlin, our president of R&D and chief operating officer, has over 24 years of experience in the pharmaceutical industry, including biopharmaceutical R&D, manufacturing and quality management. For more details, see "Directors, Supervisors and Senior Management". In addition, we actively communicate with the competent authorities for overseas clinical trials. For example, we actively communicated with the FDA and the EMA regarding the overseas clinical trial plans and relevant applications. We also engaged a reputable CRO in the EU to conduct the Phase 1 clinical trial of BA6101, including project management, medical and safety monitoring, site monitoring, clinical conduct, etc. We plan to continue to engage reputable CROs to conduct overseas clinical trials in the future.

The following diagrams set out the components of our R&D process and the role of our R&D platform in each process:



Our research and development costs were RMB236.3 million and RMB231.6 million for the years ended December 31, 2020 and 2021, respectively, and RMB111.6 million and RMB169.1 million for the six months ended June 30, 2021 and 2022, respectively. We expect that our research and development costs will increase in line with the growth of our business in the future.

Our R&D capabilities and achievements have been widely recognized by stakeholders, including the PRC government. We have received various government grants to facilitate the ongoing development of our drug candidate pipeline. As of December 31, 2020 and 2021 and June 30, 2022, we had government grants under non-current liabilities of RMB2.8 million, RMB1.8 million and nil, respectively.

Discovery

Our R&D process begins with the discovery of new drug candidates. Our antibody discovery team focuses on identifying and validating potential therapeutic molecules that can cure or delay the progress of a disease by modulating or targeting one or more specific protein targets, which plays critical roles in particular metabolic or signaling pathways. We also closely follow international frontier life science progress to identify any product with pharmaceutical activity and high market potential.

Our drug discovery function is led by a key scientist team with rich experience in drug discovery and development. Many team members have prior work experience at leading pharmaceutical companies. Our drug discovery platforms include human antibody transgenic mouse and phage display technology, bispecific T-cell engager technology and ADC technology platforms.

Antibody candidate generation, screening and engineering

Once the desired protein targets are identified and verified, we initiate the candidate generation and screening process by immunizing human antibody transgenic mice with the target proteins followed by phage display technology for generating and screening potential human antibodies.

After preliminary functional analysis, potential clones were picked for sequencing. Antibody heavy chain variable region and light chain variable region of each clone were amplified respectively and converted to an intact IgG for production and characterization. Flexible and diverse phage display-based screening methods enable us to identify candidates with diverse epitopes, high affinity and high specificity. Bispecific antibodies that combine two or more monoclonal antibodies are constructed and produced with suitable forms.

Technology platforms

Human antibody transgenic mouse and phage display technology

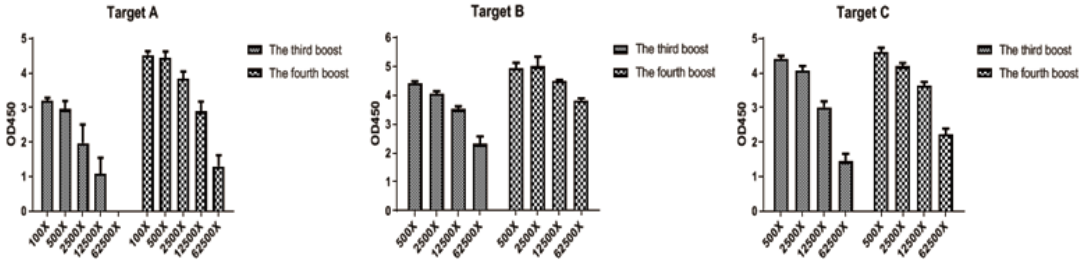
Our antibody discovery platform mainly consists of human antibody transgenic mouse and phage display technology. We have developed the BA-huMab® platform that generated a diverse repertoire of human monoclonal antibodies. Antibody humanization usually requires much work and time. With BA-huMab® and phage display technology, no humanization work is needed for antibodies, which lowers the risks in drug development and greatly improves our R&D efficiency.

BA-huMab® platform

More and more human antibodies are being approved for marketing or entering clinics compared with humanized antibodies, and most of human antibodies are derived from humanized transgenic mice. We are one of the few Chinese companies that own proprietary transgenic mice platform, and have the ability to upgrade the platform continuously. BA-huMab® is becoming an important driver of antibody discovery.

Our human antibody transgenic mice developed under the BA-huMab® platform contains over 30 human antibody κ light chain variable region genes, 110 human antibody heavy chain variable region genes (IgM&IgG1). BA-huMab® platform can directly generate human antibodies without humanization, which significantly accelerates antibody discovery process and decreases immunogenicity risks. BA-huMab® is able to elicit an immune response quickly and produces a high antibody titer after immunization. We have successfully identified potential candidates of over 10 projects through the human antibody transgenic mice of BA-huMab®, with high affinity and high specificity. For example, candidates for LY-CovMab, BA1105, BA1106 and BA1201 were developed under the BA-huMab® platform. The following diagram shows the antibody titers after immunization with different target proteins.

Detection of antibody titers after immunization with different target proteins by BA-huMab® mice



Phage display technology platform

Our phage display technology platform was used to get single chain fragment variable ("**ScFv**") candidates with excellent binding or functional activity to one target protein, by constructing a phage library that displays the ScFvs on the surface of the phage and subsequent high-throughput panning. Our phage display based screening platform features the following advantages:

- Efficient animal immunity technology. Both the optimized immunization adjuvant and diverse immunization strategies contribute to high antibody titers in immunized mice, which are ideal sources of therapeutic antibodies.

- Mature phage library construction technology. With the proprietary mature phage library construction technology, as many antibody genes as possible can be displayed on the surface of the phage. Quality of phage libraries is strictly controlled with the capacity of immunized libraries larger than 10^9 and sequence accuracy rate higher than 95%.

- High-throughput and diverse phage based panning strategies. Flexible and diverse phage display-based screening strategies enable us to identify candidates with diverse epitopes, high affinity and high specificity.

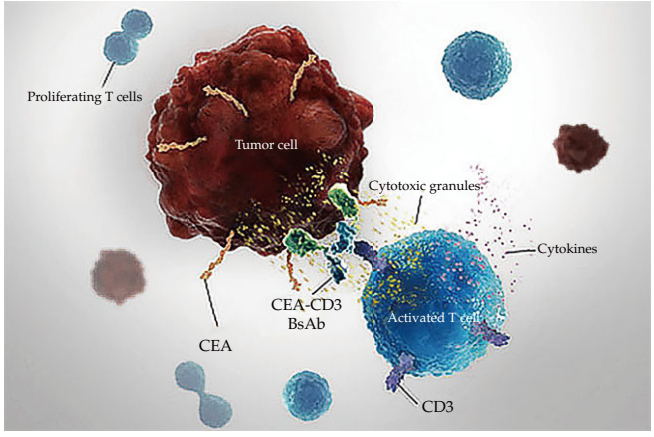
- Diverse evaluation capabilities for antibodies or antibody fragments. A variety of methods related to biology or physicochemistry have been established for antibody characterization.

Our phage display platform has been continuously optimized with higher efficiency. We have successfully identified through the phage display platform potential candidates of over 10 targets, with high affinity and high specificity.

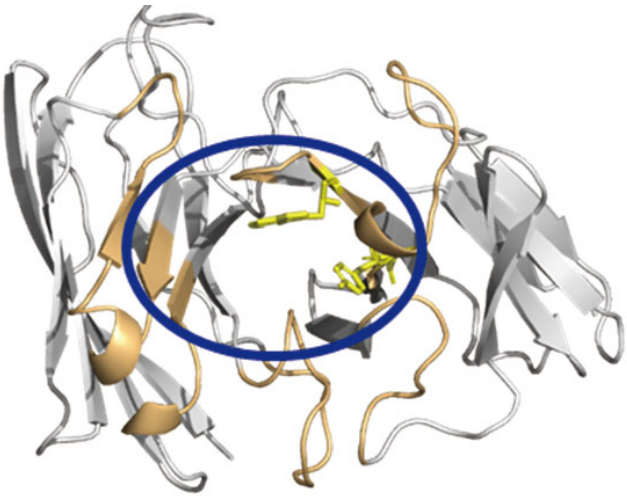
Bispecific T-cell engager technology platform

T-cell engager antibodies targeting both tumor antigens and T-cell CD3 are one of the most active areas in the development of bispecific antibodies. Bispecific T-cell engager can effectively eliminate tumor cells expressing target proteins, increase the infiltration of immune cells into tumor tissues, and stimulate cold tumors turning into hot tumors. The combination use of the bispecific T-cell engager with immune-checkpoint inhibitors can produce a better therapeutic effect for cold tumors. However, bispecific T-cell engager has many challenges during the R&D process, such as dose limitation, fatal CRS, poor efficacy or off-target toxicity risks. To address these challenges, we established the bispecific T-cell engager technology platform with our proprietary bispecific T-cell engager format retaining Fc region. Our studies revealed that our bispecific T-cell engager format exhibits high avidity with tumor target antigen by bivalent binding to achieve better drug efficacy, and low affinity with T cells by monovalent binding to lower toxicity. Meanwhile, our bispecific T-cell engager technology platform further reduces CD3 antibody binding affinity, therefore significantly reduces the risk of CRS.

Mechanism of action of CEA/CD3 bispecific antibody

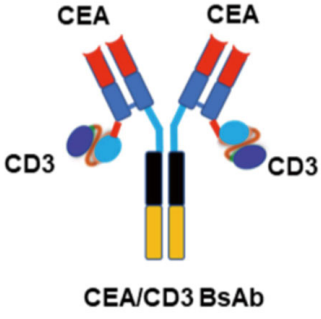


Bind domain of CD3 antibody



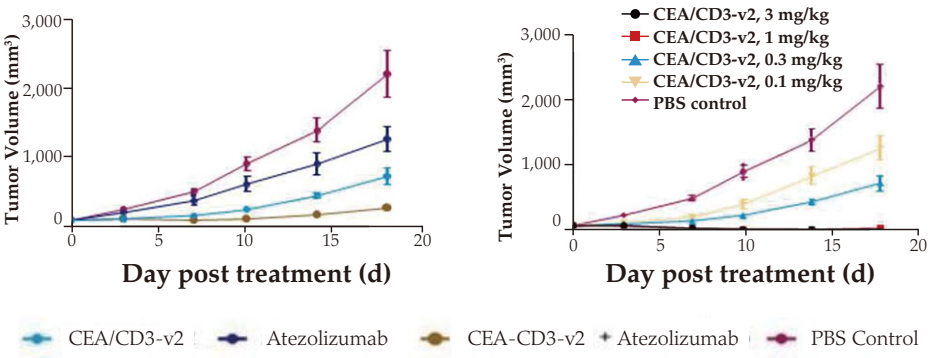
BA1202 (CEA/CD3 bispecific antibody) is our first drug candidate under development with our bispecific T-cell engager technology platform. BA1202 effectively deleted tumor cells expressing CEACAM5 protein by recruiting CD3+ T cells and increases the infiltration of immune cells into tumor tissues. Pre-clinical research data showed that BA1202 had strong cellular cytotoxicity against tumor cells, and significantly reduced the release of cytokines, and exhibited a better therapeutic potential.

The structure of CEA/CD3 bispecific antibody



Source: An optimal antitumor response by a novel CEA/CD3 bispecific antibody for colorectal cancers, Antibody Therapeutics, 2021

The anti-tumor efficacy of CEA/CD3 bispecific antibody



In addition, we have multiple bispecific antibody pipelines that are under development with similar optimized formats and low affinity CD3 antibody. *In vitro* and *in vivo* studies have preliminarily confirmed that these products showed similar therapeutic advantages. We plan to accelerate the development of these products into the clinical stage.

ADC technology platform

We have established the ADC technology platform covering the whole process of ADC discovery and development. Our ADC technology platform includes the following main functionalities: (i) design, synthesis and screening potential ADC linker-payload; (ii) identification of potential internalized antibodies; (iii) diverse antibody conjugation technologies; (iv) evaluation of ADC *in vitro* and *in vivo*; and (v) process development and quality analysis for ADC products. By conjugating a cytotoxic payload to an antibody with a cleavable or non-cleavable linker, ADC was designed to deliver cytotoxic payloads to the tumor tissue with a high specificity, maximizing their efficacy and minimizing their systemic exposure. The ADC technology platform enables us to discover and develop ADC candidates efficiently and quickly, which contributes to the diversification of our technology platform and portfolio. We are developing several ADC projects, among which BA1301 will enter into the clinic trial in the near future. BA1301 is an ADC combining a novel Auristatin analog with an antibody via the bridging conjugation technology, which showed high efficacy in mouse model and excellent tolerance in rats and cynomolgus monkeys in the pre-clinical research.

The key to ADC development is to get three distinct components to work together: (i) a monoclonal antibody that binds to an protein overexpressed on the surface of tumor cells and demonstrates a high internalization capacity, (ii) a cytotoxic molecule with medium-high potency, and (iii) a stable linker between the antibody and cytotoxic molecule, which should be stable in the blood circulation and release the cytotoxic molecule once internalized into the tumor cells. Due to the complexity of the ADC structure, its development and production process are more complicated than traditional antibodies.

In order to facilitate the identification of the suitable linker-drug for an ADC project, we have established a linker-drug library combining diverse linkers and toxin molecules. Novel linkers and toxins are continually added to keep the library evolving. In the future, new ADC products will be continuously added to our pipeline.

***In vitro* and *in vivo* functional studies**

Our R&D team has set up a series of *in vitro* functional assays and *in vivo* animal models for evaluation of antibody candidates. The binding profiles of these candidates related to affinity and epitope were analyzed by a series of optimized assays such as surface plasmon resonance ("**SPR**") assay, flow cytometry based cell binding assay, ELISA-based blocking assay and competitive binding analysis on a ForteBio system, etc. Various cell-based assays are designed to evaluate the biological functions of antibody candidates such as antibody dependent cellular cytotoxicity assay, antibody internalization capacity assay and cytokine release assays.

Various mouse models were used for the efficacy study of antibody candidates. After antibody administration in mouse models, data of tumor growth was collected for efficacy study. We have established multiple xenograft xenografted mouse tumor models as well as multiple syngeneic mouse tumor models covering multiple cancer types. In addition, a specified CD3-humanized mice were developed and this *in vivo* mouse model was used for CRS toxicity evaluation of the bispecific T-cell engagers.

Cell line construction

Following *in vitro* and *in vivo* studies, a high-quality production cell line is needed to produce the antibody candidate, as the quality of the cell line directly affects manufacturing cost as well as the quality of the final product. We have been developing and implementing high-yielding cell line technologies through the CHO cells expression system. The CHO cell expression system, a mainstream expression system in the biopharmaceutical industry, has the following advantages: (i) its post-translational modification functions are very similar to humans; (ii) it is easy to manipulate and modify to meet usage requirements; (iii) it can maintain high protein expression levels in chemically defined cell culture media; and (iv) it shows better safety in respect of human pathogenic viruses.

We have a proprietary platform focusing on CHO cell line development. The platform has a complete vector sequences, a clear host cell history and a complete proof of monoclonal origin. Using our CHO cell expression system, we have developed and constructed the cell lines for three monoclonal antibody candidates, namely, LY-CovMab, BA1106 and BA1301. The cell lines obtained from this platform for commercial production generally meet the requirements of primary regulatory authorities around the world. For example, both our master cell bank and working cell bank of LY-CovMab are prepared in compliance with applicable GMP standards, and tested and characterized in accordance with International Council for Harmonization ("**ICH**") Q5A guidelines on the viral safety evaluation of biotechnology products derived from cell lines of human or animal origin, as well as in agreement with the United States, the EU and PRC pharmacopoeia guidelines.

After the optimization of the screening process, we can obtain research cell bank within three months, and the average expression level of monoclonal antibodies are greater than 4g/L, which meets the needs of CMC development.

For cell line construction, we use our cell line development and screening technology platforms to efficiently identify individual cell lines with high productivity, quality, and stability. We have an excellence-pursuing professional technical team and advanced equipment for our stable cell line development and screening platforms, and will increase our R&D investment to build better technical platforms and accelerate the R&D progress.

To enrich our CHO cell line development platform, on September 28, 2020, we entered into a non-exclusive license agreement with a cell engineering tools and services provider who is an Independent Third Party. According to the agreement, the supplier granted a non-exclusive, non-transferable and non-sub-licensable license for a term of ten years to us to (i) use its CHO cell lines, unmodified descendants and alterations to generate protein expressing line (the "**Protein Expressing Line**") which is for the purpose of producing our products; and (ii) make and use or sub-license third parties to make and use the products derived from the Protein Expressing Lines, including clinical trials, IND application and commercialization of the products. We will solely own all intellectual property rights of all results to underlying data and conclusions drawn from studies from the use of the supplier's CHO cell lines and the derivatives, and all discoveries, inventions or other intellectual property from our studies from the use of the Protein Expressing Lines and the derivatives as well as all relevant patents and patent applications filed by us. This agreement may be terminated for cause upon written notice by either party if the other party is in breach of its material obligations due to its fault which has not been cured within 90 days after notice of cure request.

Process development

Process development consists of upstream processes and downstream processes.

Upstream process

For the upstream process, we developed and characterized the cell culture process for antibody manufacturing for non-clinical, clinical, and commercial purposes. We use our upstream process development platform to efficiently screen cell culture media, optimize seed culture expansion and facilitate fed-batch process development, as well as to expedite early-stage process development. We select the media with better protein yield and quality by media screening experiments. In the media screening experiments, we preferentially select domestic commercial media to reduce the manufacturing cost of the antibody. After determining the media, we carry out the process development and scale up of the bioreactor to study the process parameters such as pH, temperature, dissolved oxygen, stirring speed, etc. Through cell culture process development and characterization, we improve the productivity, quality and robustness of our process amplification.

Towards the later phases of development for each drug candidate, all critical process parameters are investigated and well-defined to ensure that all CQAs meet ICH Q8 guidelines. We perform cell culture process characterization and define the ranges of critical process parameters in order to ensure the robustness of our process amplification and the consistency of product quality. Moreover, in addition to the traditional fed-batch culture process above, we have developed N-1 stage perfusion mode cell culture processes which enable generating high density cell cultures, in order to increase the yield and improve productivity, and in turn reducing the per-unit cost of production as well as the capital requirements of our manufacturing facilities.

Downstream process

For the downstream process, we have established a comprehensive process development platform based on a common sequence of unit operations to obtain the clarified harvest by centrifugation and depth filtration. Then the target proteins are directly captured from the clarified harvest by protein A affinity chromatography, and achieve the purpose of concentration. The low pH elution from the protein A chromatography step also provides virus inactivation. Two chromatographic polishing steps are used to further reduce impurities. One of the polishing steps is invariably anion exchange chromatography, and the second polishing step is typically cation exchange chromatography or hydrophobic interaction chromatography are used. The remaining process steps include virus filtration and ultrafiltration/diafiltration and drug substance preparation. The standardized process is efficient and robust, which enables the rapid convergence of future industrial production around a similar process flowsheet. The manufacturing process can be adapted to different products with slight adjustments around base platforms which facilitates the efficient development of multiple drug candidates with high speed and quality. In addition, by using a platform process, manufacturing plants designed for the production of one mAb can usually be readily adapted to produce others. As a result, they have relatively low manufacturing costs and benefit from the flexibility of production at either in house or CDMOs.

Formulation development

Our formulation development platform enables us to efficiently develop the formulation and process of the drug products. We conduct development studies, formulation studies including pH buffer system screening and excipient screening and manufacturing process studies in the pre-clinical study stage, and conduct formulation optimization and process characterization studies in the later stage to determine the range of key process parameters to ensure product quality.

Structural, physicochemical, functional characterization and quality study

We have developed a variety of advanced and orthogonal analytical methods to elucidate the antibody structures and analytical comparability and similarities of the product candidates. The studies include characterization and evaluation of primary and higher-order structures, purities, heterogeneities, impurities, physicochemical and biological properties. We apply the results of such characterization analysis to evaluate the product quality attributes ("**PQAs**") of these product candidates as well as their safety characteristics. CQAs are determined through PQA testing and examination for safety and efficacy based on the mechanism of action of the product in accordance with ICH Q8 and quality target product profile. We can manufacture the drug substance and the drug candidates under a stable manufacturing process. Subsequently, the release and stability study including real-time, accelerated and stress conditions will be performed to develop the shelf life of the products and storage conditions.

Analytical and bio-analytical method development

We leverage our analytical and bio-analytical method development processes and platforms to support all of our R&D processes.

Analytical method technology platform

As described in the steps above, our overall methodology for each product candidate is closely examined and adjusted for quality monitoring and process development, and we are developing advanced technologies and methods for evaluating CQAs to ensure the quality, safety and efficacy of our drug candidates.

We also perform comparative analyses in accordance with ICH Q5E guidelines to demonstrate comparability of products from different processes, as well as with biosimilar regulatory guidelines of China, the EU and the United States for analytical similarity between biosimilar and reference product. To this end, we have developed a number of analytical technology platforms including liquid chromatography-mass spectrometry ("**LC-MS** "), high-performance liquid chromatography ("**HPLC**"), capillary electrophoresis ("**CE**"), imaged capillary isoelectric focusing ("**icIEF**"), ELISA, Differential scanning calorimetry ("**DSC**"), circular dichroism ("**CD**"), fourier transform infrared spectroscopy ("**FTIR**") methods for screening and determination of CQAs of biosimilar and innovators. Furthermore, we conduct analytical similarity studies between biosimilar and reference products based on totality of evidence. Besides extensive characterization analysis in comparability studies as described above for biosimilar and reference products, we also follow a number of other established principles in biosimilar regulatory guidelines in our analysis, including the principle of comparison, principle of consistency, principle of comprehensive analytical similarity evaluation and principle of step-wise approach. We also conduct comparability studies for products from different processes using extensive qualified methods in accordance with ICH Q5E in order to demonstrate consistency in product quality by reference to comparative analyses of structure, purity, physicochemical properties, biological activities and immunological characteristics, product- and process-related impurities and stability.

We are also developing gas chromatography-mass spectrometry ("**GC-MS**"), LC-MS, ICP-MS methods and multiple-solvent extractable models for the determination of extractables and leachables, as well as step-wise procedures for toxicological evaluation of the identified extractables and leachables.

Bio-analytical and immunogenicity analysis platforms

Our bio-analytical platform research includes multiple detection principles: optical density ("**OD**"), fluorescence, luminescence, electro-chemiluminescence, homogeneous time-resolved fluorescence ("**HTRF**"), surface SPR, biolayer interferometry ("**BLI**"), flow cytometry and so on. We utilize our bio-analytical platforms for bioassay, PK, PD and immunogenicity evaluation. A generic assay is used to analyze the circulating drug concentrations for PK assessment in dosed animals of pre-clinical pharmacology and toxicology studies. The platform technology is species-independent. We also use an immunoassay-based multiplexing assay specifically designed for antibody combination therapies, which enables simultaneous analyses of drug concentrations of more than one antibody drug.

With respect to immunogenicity assessment, we utilize a variety of methodologies in conjunction with a specifically designed sample pre-treatment step to identify and subsequently characterize ADA, including NAb determination, with adequate drug tolerance and specificity.

Clinical development

Following the receipt of IND approval from relevant regulator, we may commence human clinical trials. We closely manage all stages of clinical trials, including clinical trial design, implementation, in-house production of drug candidate samples used and the collection and analyses of trial data. As of the Latest Practicable Date we had a total of 13 drug candidates, 11 of which had entered or completed clinical trials or received the IND approvals from the CDE, comprising one drug candidate with BLA approved, three in Phase 3 clinical trial, one in Phase 2 clinical trial, four in Phase 1 clinical trial, and two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU. Both the EMA and the FDA suggested if the comprehensive quality similarity is established between BA1102 and Xgeva® as well as between BA6101 and Prolia®, and non-clinically and clinically it can be proved that BA6101 is similar to Prolia®, they will agree that the results of Phases 1 and 3 clinical trials of BA6101 in the EU can support the extrapolation of its indications to all indications of Prolia® and Xgeva®. This demonstrates our strong capability to efficiently and successfully conduct a large number of clinical trials simultaneously, including multiple late-stage clinical trials. We have committed significant resources to achieve this, with 35 clinical medical affairs staff as of June 30, 2022, many of whom have extensive experience and know-how in clinical trial practice.

We determine the location of our clinical trials based on a number of factors, including whether there are potential business opportunities in a particular jurisdiction, the regulatory environment in that jurisdiction and access to patients for clinical trials, as well as our long-term marketing strategy.

We have developed clear and focused clinical trial strategies to ensure that we can develop and launch our drug candidates in an expeditious manner, including by strategically choosing differentiated indications for clinical trials, facilitating the clinical recruitment process and controlling related costs, and targeting different biologics markets geographically. We bolster these capabilities with a strong network of domestic partners for clinical trials. Our clinical development team has entered into long-term partnerships with numerous hospitals and physician communities located in different regions of China, which give us access to readily available clinical trial facilities and services. We believe the size and geographic diversity of these facilities provide us with a significant advantage in implementing large-scale clinical trials and also enable us to conduct multiple concurrent clinical trials.

Engagement of third parties in research and development

We engage experienced and qualified third parties such as CROs, CDMOs and hospitals to manage, conduct and support our pre-clinical studies and clinical trials in China and the EU, which is in line with the general practice in the industry.

The following table sets forth the number of third parties including CROs and CDMOs that we procured services from during the Track Record Period.

	For the year ended December 31,		For the six months ended June 30,
	2020	2021	2022
CRO	104	50	33
CDMO	2	2	1

While we carry out much of our research and development work in-house, we also engage Independent Third Party CROs who provide us with a range of technology and services necessary for complex pre-clinical studies and clinical trials. We have long-term relationships with a number of reputable CROs. We select CROs based on a number of factors, including their quality, reputation and research experience. We monitor the CROs to ensure they perform their duties to a standard in line with our protocols and industry benchmark to safeguard the integrity of the data collected from the trials and studies.

The following table sets forth typical terms of our agreements with CROs:

Services:	The CRO provides services related to pre-clinical studies or clinical trials in certain phases as specified in the agreement or a work order.
Term:	The CRO is required to complete the work with an agreed time period.
Payments:	We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.
Intellectual property rights:	All intellectual property rights arising from the clinical trials are owned by us. For the agreements involving hospitals, both of hospitals and us have coauthorship rights to the papers published based on the findings.
GCP compliance:	We require the CRO to conduct clinical trials in accordance with international GCP standards. Typically, we require the CRO personnel handling our clinical trials to hold GCP certification or have GCP training experience.
Confidentiality:	The CRO and relevant hospitals have non-disclosure obligation, and undertake not to disclose our trade secrets or other business information to any third party without our prior written consent.
Non-competition:	During the term of the agreement and for a period of certain years after the end of the term of the agreement, the CRO and we shall not approach any of each other's employees or consultants to induce them to quit the CRO or us or any of the affiliates and engage in a business that competes with that of their original employer.
Termination:	We may terminate the agreement in the event of, among others, (i) any material breach by the CRO; or (ii) any other breach by the CRO that is not remedied within a prescribed time-period.

The following table sets forth the division of roles and responsibilities between the Group and CROs at each stage of development of our Core Products in China and overseas:

	Responsible party	Pre-clinical	Phase 1	Phase 3
Our biosimilars Core Products (i.e., BA1102 and BA6101)	Group	Method development of production process and quality analysis, pharmacodynamic studies, communication with the CDE, the IND filing, etc.	Optimization and confirmation of production process and quality analysis method, communication with the CDE, production of clinical samples, clinical program design, clinical organization and operation, etc.	Optimization and confirmation of production process and quality analysis method and technology transfer, clinical program design, communication with the CDE, etc.
	CROs	Cell line development, cell bank assay, virus removal validation, non-clinical research (pharmacokinetics, toxicokinetics, toxicology and efficacy), etc.	Clinical trial research, biological sample testing, data management and statistical analysis. Project management, medical and safety monitoring, site monitoring, clinical conduct, communication with the overseas competent authorities, etc.	Clinical trial research, data management, statistical analysis, virus removal verification, one-time system compatibility research, etc.
Our innovative Core Product (i.e., LY-CovMab)	Group	Antibody screening, cell line development as well as method development of production process and quality analysis	Clinical program design, clinical organization and operation as well as quality control and supervision of clinical programs	Clinical program design, clinical organization and operation, quality control and supervision of clinical programs

Responsible party	Pre-clinical	Phase 1	Phase 3
CRO	Main cell bank and unprocessed bulk sample detection, virus clearance process research, gene sequencing, non-clinical research (pre-test and safety assessment) as well as *in vitro* efficacy research	Clinical trial research, biological sample testing, data management and statistical analysis	Clinical trial research

While in recent years we have primarily manufactured product candidates in-house in China for our clinical trials, in case of facing a shortage of our pilot production capacity, we have engaged CDMOs to produce small quantities of product candidates for our clinical trials in China. Going forward, we may still consider outsourcing excess pilot production needs to CDMOs from time to time, if necessary. We select our CDMOs by reviewing a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and the financial terms offered by them.

The following table sets forth typical terms of our agreements with CDMOs:

Services:	The CDMO provides us with services such as cell line transfer, cell line construction, development of upstream process and downstream process, pilot production, etc.
Term:	The CDMO is required to perform its services within the prescribed time limit set out in the agreement and in accordance with the key performance indicators agreed by both parties.
Payments:	The CDMO bills us in accordance with milestones agreed by the parties and usually we are required to make payments within certain period of time from the invoice date.
Intellectual property rights:	All intellectual property rights arising from the clinical trials are owned by us.
GMP compliance:	We require the CDMO to produce our product candidates in accordance with GMP standards.

Confidentiality:	The CDMO has non-disclosure obligation, and undertake not to disclose our trade secrets or other business information to any third party without our prior written consent.
Termination:	We may terminate the agreement in the event of, among others, (i) any material breach by the CDMO; or (ii) any other breach by the CDMO that is not remedied within a prescribed time-period.

MANUFACTURING

As of the Latest Practicable Date, we had a pilot and commercial production site for antibody products in Hi-tech Industrial Development Zone in Yantai (煙台高新區), Shandong province, which had a total GFA of approximately 33,504.1 sq.m. We own the underlying land use rights and buildings for the Yantai Site and all of the plant and equipment within the site.

The manufacturing process of biologics includes drug substance manufacturing process and drug product manufacturing process, which applies to both pilot and commercial production. Drug substance manufacturing process generally includes cell culture production and protein purification, while drug product manufacturing process mainly includes filling, inspection, labeling and packaging of samples and final products. Our pilot production lines provide samples in small quantity for safety evaluation studies at Phase 1 and 2 clinical trials and samples for manufacturing process validation, while our commercial production lines mainly produce products in large batches for selling purpose. The Yantai Site houses a number of production lines which are used for (i) drug substance manufacturing process, with a capacity of total 1,700L for pilot production (comprising three 500L and one 200L single-use bioreactors) and 8,000L for commercial production (comprising two production lines each with two 2,000L single-use bioreactors), and (ii) drug product manufacturing process, for both pilot and commercial production, consisting of (a) the vial filling formulation line with a designed production capacity of 2.5 million vials per annum, and (b) the pre-filled product formulation line of 3.5 million pre-filled syringes per annum.

For drug substance manufacturing process, we may concurrently produce the same product in different bioreactors, which is common practice in the biopharmaceutical manufacturing industry, especially for antibody production. Each bioreactor uses identical operating and control systems, and each is required to undergo the same set of equipment and process validation procedures before activation. This helps to ensure that our products are manufactured according to the same quality even when such manufacturing takes place across multiple bioreactors. As a result of this uniformity in hardware and process, we do not expect to encounter any material difficulties in maintaining consistency of production quality across different bioreactors, nor any material increases in production costs.

For drug product manufacturing process, the Yantai Site is equipped with two automatic formulation filling lines. The production lines have a high level of sterility assurance, which can meet the production of both vials and pre-filled packaging products at the same time. The designed production capacity of vials filling line is 2.5 million units per annum, and the designed production capacity of pre-filled products is 3.5 million units per annum. In 2021 we produced 303,294 vials and 36,296 pre-filled syringes for both our clinical trials and commercialization representing a utilization rate of 12.0% and 1.0% of the vial filling formulation line and the pre-filled product formulation line, respectively, which is calculated by dividing the actual production volume by the designed production capacity per annum. The low utilization rate of the production capacity of vials filling line in 2021 was due to our commencement of commercial sales of Boyounuo® (BA1101) in May 2021 which was still in the ramp-up period, and as we are expanding our distribution network, we expect there will be more market demand for Boyounuo® (BA1101) and a higher utilization rate. The pre-filled product formulation line was mainly used for the manufacturing process validation of BA6101 in 2021, which only involved small batch production on a need basis. We expect the utilization level of the pre-filled product formulation line will increase after BA6101 is commercialized. The Yantai Site is also equipped with inspection and packaging equipment to meet the needs of vials filling and pre-filled products in different packaging forms.

As of June 30, 2022, we had a total of 305 personnel engaged in manufacturing, 151 of whom were responsible for Phase 3 clinical and eventual commercial production. In addition, of our 253 R&D employees, 77 were responsible for pilot production for IND filings and Phase 1 and Phase 2 clinical trials. As of the same date, we also had an engineering and environment, health and safety team of 46 personnel responsible for environment, health and safety, operation and maintenance of equipment, facilities and instruments as well as public works systems, development of new and reconstruction projects, etc. As maintaining and building up our talent pool is one of our key success factors, we have training and development programs in place to develop our manufacturing teams to meet our commercialization and expansion needs. We further plan to digitalize our operational systems for higher production turnover and reducing energy consumption by having strategic cooperation with technology companies. For example we reached strategic collaboration arrangements with Jerei to accelerate the process of our digital construction. For more details, see "— Manufacturing — Strategic collaboration with Jerei".

We procure a variety of advanced manufacturing-related equipment from well-known international pharmaceutical equipment suppliers. We utilize both single-use technologies and stainless steel technologies in the production process. For example, we use single-use bioreactors for the expansion of cell culture in the upstream process. We also use stainless steel media preparation tanks and stainless steel media storage tanks for preparation and storage of large volume cell culture media in upstream process. In addition, we use stainless steel equipment in the downstream process, including large volume buffer solution preparation tanks, large volume buffer solution storage tanks, harvest tanks, low PH incubator tanks, anionic protein sample tanks, cationic protein sample tanks, nanofiltration sample tanks and ultrafiltration sample and circulation tanks. We believe that, single-use bioreactors possess certain advantages, including shorter downtimes, reduced cleaning and sterilization efforts, a significantly lower risk of cross contaminations, flexibility and easy shifts in portfolios based on market needs. The advantages of stainless steel equipment are reduction in commercial production costs, environmentally friendly and high degree of automation. Considering the advantages and disadvantages, we utilize both single-use technologies and stainless steel technologies in the production process.

During the Track Record Period, we procured production equipment from time to time. Our production equipment is generally aged three years. We calculate depreciation on our equipment using the straight-line method over their estimated useful lives, which are five to ten years. We conduct regular maintenance and repair work and review their useful lives on a monthly, quarterly and annual basis.

It is expected that most of our Core Products and BA9101 will launch in the near future, i.e., BA6101 in November 2022, BA1102 in the first quarter of 2024 and BA9101 in the second half of 2025 in China. In addition, we are expanding our distribution network for Boyounuo® (BA1101). To meet the expected demand for Boyounuo® (BA1101), the drug candidates to be launched and clinical trials of our product candidates, we plan to expand our manufacturing capacity significantly by developing additional production lines for drug substance manufacturing process in the Yantai Site, which are currently under construction, including four 500L single-use bioreactors for pilot production and two production lines each with three 2,000L single-use bioreactors for commercial production, which are expected to be completed in 2024. We designed the production lines for drug substance manufacturing process to incorporate substantially similar manufacturing equipment, technologies and processes as those used and to be implemented at our existing production lines. We expect the two production lines for drug substance manufacturing process once completed to support our future commercial needs. The estimated budget for the construction of production lines for drug substance manufacturing process is RMB407 million, which will be mainly funded from our working capital. It is estimated that RMB143 million will be due in 2022, with the rest to be paid in the future three years.

Chemistry, manufacturing and control

The focus of drug discovery gradually shifts to quality as the development process enters human clinical trials after IND application. The methods in controlling the drug substance quality arise from multiple functions as described in the R&D processes above. The control and documenting of these methods are known as CMC, the details of which are regularly updated and reported to the relevant regulatory authorities. We take pride in our strong CMC capability which is the backbone of the high quality and cost efficiency we have maintained throughout the process of our drug development and commercial production, especially in cell line development, upstream and downstream process development, analytical and bio-analytical method development as well as technology transfer. Our CMC function establishes practical qualitative and quantitative standards for us to maintain product quality and effectively progresses drug discovery to actual manufacturing. It also assists in delivering products in accordance with quality standards which meet both regulatory and commercial requirements.

Our CMC team is structured as a project management team consisting of members from different teams, including our R&D, quality management, pilot production, manufacturing and regulatory affairs teams. We designate a project leader to coordinate and promote the progress of project implementation to ensure clear allocation of responsibility and seamless transition with extra traceability, as development progresses from early stage to commercialization.

Our CMC team currently manages eight clinical-stage drug candidates simultaneously, and we plan to further expand these capabilities as we advance more drug candidates to clinical development and expand our pipeline.

We employ a robust quality management system for the Yantai Site that meets various quality standards such as GMP set by the relevant regulatory authorities of China and the EU and had passed a number of audits in China and the EU.

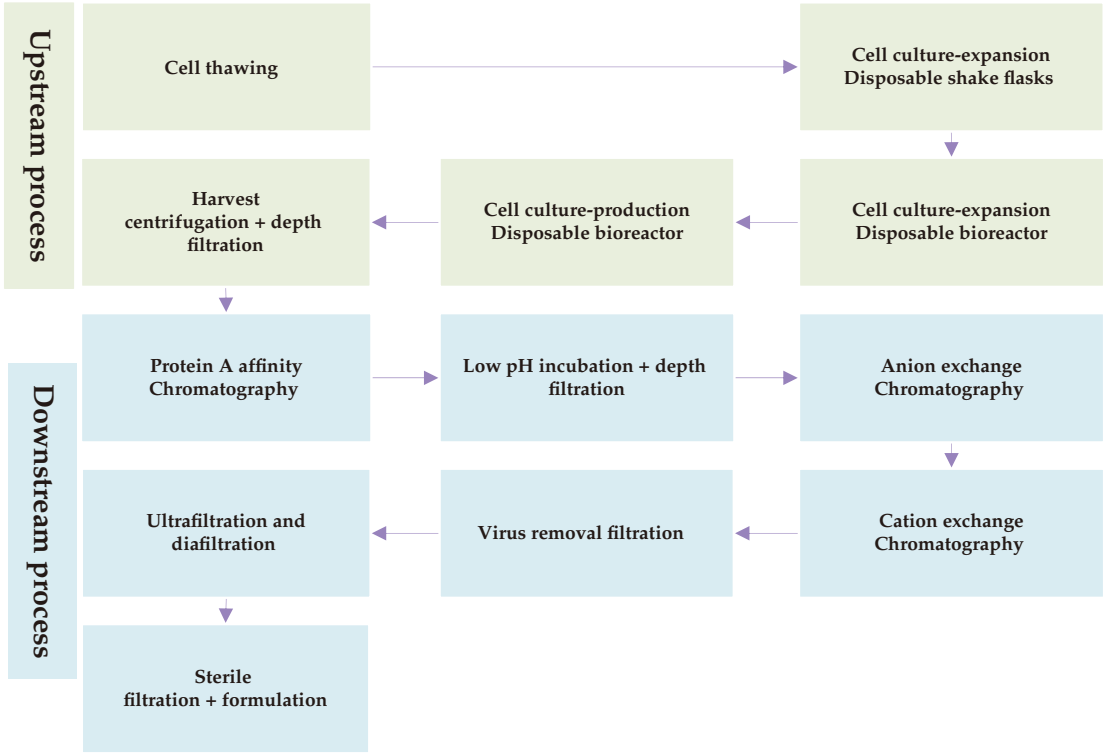
As a part of our strategy of affordable innovation, we aim to carefully control costs and improve quality throughout the following measures: (i) local procurement of consumables and materials by sourcing from PRC enterprises which have a track record of strong product quality and which meet our quality guarantee requirements, such as disposable storage bags, filters, culture medium, chromatography system, chromatography column, etc., after a comprehensive risk assessment to reduce production costs and ensure product quality and progress and supply chain security; (ii) production process upgrade by using technology to lay out the production process upgrade strategy in advance. For example, we laid out the production process upgrade strategy for Boyounuo® (BA1101) with the emerging perfusion technology in advance. As of the Latest Practicable Date, the upgraded production process had entered the stage of technology transfer. We have started engineering run in June 2022, and will start process validation in the second half of 2022. It is expected that the batch production will increase by two to three times; (iii) continuous production process optimization. For example, after Boyounuo® (BA1101) was approved for sales, we carried out a series of production process optimization actions to reduce the rejection rate and improve the product yield by optimizing the structure of the bottle mouth of the vial to reduce the warping rate of the

filling and stoppering process, optimizing the low liquid level of the buffer tank to improve the filling yield and continuing to strengthen the operation skills training of personnel in filling and capping positions, and reducing the waste generated by operations; and (iv) expansion and upgrade of production lines. For example, we are expanding the production lines for drug substance manufacturing process from the existing two production lines each with two 2,000L scale by adding additional two production lines each with three 2,000L scale, which can further shorten the batch production time and greatly increase the production capacity.

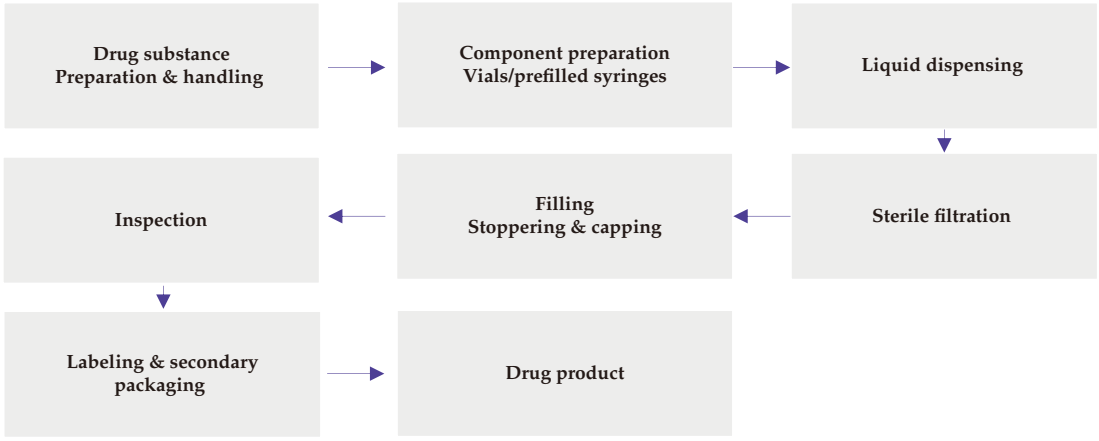
Manufacturing process

The following charts set out a summary of our overall manufacturing process of our products and product candidates, which takes approximately 50 days:

Drug substance manufacturing process



Drug product manufacturing process



Our manufacturing operations team closely collaborates with cross functional teams, such as quality assurance, quality control, pharmacovigilance, supply chain management and others to produce high-quality products in a reliable and safe manner, in accordance with a comprehensive set of GMP standard operating procedures in place.

These efforts and advances have enabled us to meet or exceed global regulatory requirements and regulations, including, but not limited to, the requirements of the FDA, EMA and NMPA for manufacturing. For example, our Yantai Site and accompanying quality management systems have passed multiple on-site inspections and/or audits conducted by external experts, the NMPA Shandong province Bureau, an EU qualified person for medical products in each case in accordance with exacting standards. In March 2021, we passed the GMP compliance inspection certifying our compliance with PRC GMP requirements for Boyounuo® (BA1101).

In addition, we have a bio-manufacturing innovation technology research laboratory responsible for promoting and exploration of advanced manufacturing science and technology such as alternative cell culture manufacturing technology. The developed N-1 perfusion culture technology has completed the pilot production. Under the premise of a comparable fed-batch culture CQAs, the target protein expression can be significantly increased to about three times of the current level for one product. We plan to transfer such manufacturing technology to our commercial production in the near future.

Quality management systems

We have established a quality management system that covers the entire product lifecycle from product research and development to technology transfer, commercial production, product supply management and product post market surveillance. We believe that an effective and efficient quality management system is essential to (i) ensure accurate and reliable clinical studies for our drug candidates, (ii) ensure the regulatory compliance in China, the United States and the EU, and (iii) realize the reputation and recognition of the product in the market.

Our quality management team, which operates our quality assurance, quality control and pharmacovigilance functions, consisted of 101 employees as of June 30, 2022, which was approximately 33.1% of the headcount of our manufacturing team. Its organizational structure includes quality assurance, quality control, and pharmacovigilance teams. The majority of our employees in our quality management team are staffed in our quality control laboratory, which has approximately 2,000 square meters of lab space and various instruments, which enables a broad spectrum of analytical analysis capable of supporting all aspects of testing required for the manufacturing of protein products to be used by us, from Phase 3 clinical trials to commercial production. Our employees in the quality management team generally hold at least associate degrees in biochemistry, pharmaceutical and relevant fields and have working experience with pharmaceutical and biotech companies.

We are also committed to continuously improving our quality system on an ongoing basis, with sizable investments in technical consulting, quality management, software procurement and staff training. Our quality management team holds regular meetings to review quality policies, regulatory updates, and quality issues. More significant issues are escalated to relevant department heads and our chief executive officer. We also engage domestic and overseas consultants to audit our quality management system and perform gap analyses to continuously improve our quality management system. So far, we have not encountered any significant quality issues which had any material impact on our business or operations.

Strategic collaboration with Jerei

We entered into a strategic collaboration agreement with Jerei on January 20, 2022, an Internet service company and an Independent Third Party, pursuant to which we and Jerei would begin a strategic collaboration to accelerate the process of our digital construction, including the development of simulation training software for technicians' training, the construction of a digital twin system for our production lines to acquire real-time production line data and to generate a real-time analysis for automatic production line scheduling and to further reduce energy consumption.

On March 8, 2022, we entered into a simulation training software development agreement (together with the strategic collaboration agreement entered into between Jerei and us on January 20, 2022, the "**Jerei Agreements**") with Jerei to refine and implement the development of simulation training software, pursuant to which Jerei is required to develop the simulation training software for four manufacturing processes including drug substance preparation, sterile filtration, reaction bag installation, and chromatography column packing. Jerei would also provide training and software maintenance services. Both parties may terminate the agreement in the event of, among others, any material breach by the other party.

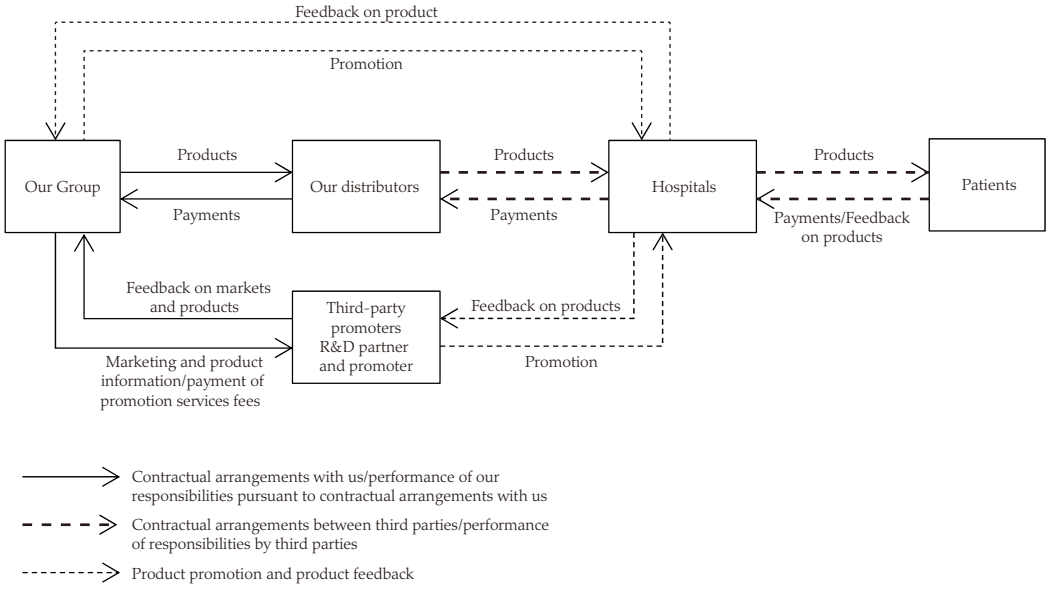
According to the Jerei Agreements, in general we and Jerei will jointly own the intellectual property rights of the simulation training software and the digital twin system to be developed, and we will own the intellectual property rights of the digital twin system if it involves our production data, proprietary technologies and other trade secrets. For the software and systems owned by Jerei and us, both of us are entitled to share on an equal basis of the profits derived from the licensing and authorization of such software and systems. Both parties have non-disclosure obligation, and undertake not to disclose any trade secrets or other business information to any third party without the other party's prior written consent.

As of the Latest Practicable Date, the simulation the training software for drug substance preparation and sterile filtration has been preliminarily completed and was in the optimization stage, and the simulation training software for reaction bag installation and chromatography column packing was under development.

COMMERCIALIZATION, SALES, MARKETING AND DISTRIBUTION

Leveraging our well-established and demonstrated commercialization capability backed by marketing strategies implemented by our dedicated sales and marketing team, we believe we are well positioned to achieve speed-to-market and rapid ramp-up of product sales. Internally, we have a dedicated in-house sales and marketing team with extensive industry experience and they develop and implement marketing and sales initiatives and plans of our product and drug candidates in their scheduled rollouts. Externally, we collaborate with various resourceful business partners which lay the foundation for our strong commercialization capability. Our collaboration with experienced third party promoters effectively publicizes and maximize market potential of our products. For example, on May 26, 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, regarding the promotion rights to Boyounuo® (BA1101), under which we agreed to grant to AstraZeneca China exclusive promotion rights in certain counties of various provinces and autonomous regions in China. Besides the commercialization of launched product, we also pay close attention to identify and maximize early commercialization opportunity of advanced drug candidates. For example, on October 28, 2020, we entered into an agreement with OcuMension regarding the promotion and commercialization of BA9101 in China, as amended by a supplemental agreement dated May 31, 2021. Last but not least, we had an extensive distribution network of 160 distributors as of June 30, 2022, penetrating selected regions and reaching more than 1,100 target hospitals and institutions in China. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China.

The following diagram illustrates the interactions among our third-party promoters, distributors, hospitals, patients and us in connection with sales, marketing and distribution of Boyounuo® (BA1101) in China as an example.



In-house sales and marketing team

Our in-house sales and marketing team is primarily responsible for the promotion of our products. As of June 30, 2022, our in-house sales and marketing team included 36 employees, with the majority having bachelor's or above degrees. Our in-house sales and marketing team has solid promotion ability and has successful experience and ability in oncology drug sales promotion, distribution channel expansion and expert network construction. The management personnel of our in-house sales and marketing team have rich experience in domestic leading enterprises. We are expanding our sales and marketing team to cover most provinces, municipalities and autonomous regions in China. As of the Latest Practicable Date, our in-house sales and marketing team included 39 employees. We believe that an in-house sales and marketing team with a relatively high level of industry knowledge and expertise is important to implement our marketing approach and to maintain our reputation and brand image.

Our marketing team currently consists of a marketing and sales team and a market access team, the respective key functions of which include:

- Marketing and sales team. Our marketing and sales team manages market data analysis, market forecast analysis for drug candidates in our pipeline and product promotion and marketing. The team also promotes our products by organizing meetings and inviting experts with deep clinical experience to share knowhow or experience, organizing meetings and inviting leading healthcare experts to consult their views on product proposition and strategies and policy changes, and collects market intelligence. It also work closely with our market access team to accelerate market penetration.

- Market access team. Our market access team participates in negotiations with government agencies and hospitals to facilitate our product to become eligible for local medical insurance coverage in China, accepted by hospitals and added to procurement lists.

Our sales and marketing personnel are required to strictly adhere to our detailed procedures, policies and guidelines. For more details, see "— Internal controls and risk management" in this section.

Third-party promoters

To supplement our in-house sales and marketing capabilities, we engage experienced third-party promoters (including AstraZeneca China) to publicize and maximize market potential of our products. We select third-party promoter based on their qualifications, reputation, marketing experience, management capabilities and hospital coverage. Third-party promoters act as our agent when performing their promoting obligations as disclosed in the following table, and they, unlike distributors, do not buy or sell our products. Third-party promoters do not enter into any contracts with customers on behalf of us. Our distributors generally do not conduct promotion activities. Our distributors are not introduced by third-party promoters, and as far as we are aware, they do not enter into any arrangement with each other for the purpose of promoting and distributing our products. There is no overlapping role between the third-party promoters (including AstraZeneca China) and distributors as promoters (including AstraZeneca China) act as agents to promote our products and, unlike distributors, they do not buy or sell our products. Our industry consultant, Frost & Sullivan, is of the view that it is in line with the industry norm to use third-party promoters to promote drug products.

We granted to AstraZeneca China the exclusive promotion rights in the designated promotion areas mainly to leverage AstraZeneca China's rich marketing resources in those areas. Therefore, our other third-party promoters do not overlap with AstraZeneca China in the designated promotion areas pursuant to our agreements with them.

Third-party promoters other than AstraZeneca China may overlap in their respective designated promotion areas to some extent, mainly because we intend to bring our products to the broader market as well as to enable our products to achieve speed-to-market to meet the market demand, by engaging with more third-party promoters reaching different hospitals and institutions so as to enhance our product visibility within a short period of time, which is also in line with our commercialization strategies. We believe not granting any exclusive promotion right in the designated promotion areas to these third-party promoters may achieve our objective more effectively.

As of December 31, 2021 and June 30, 2022, we had 12 and 27 third-party promoters providing us with promotional services, respectively. The third-party promoters are enterprises that provide marketing and promotion services and some are specialized in pharmaceutical areas. Among the 27 third-party promoters as of June 30, 2022 compared to the third-party promoters as of December 31, 2021, we had 16 new promoters and 11 pre-existing promoters providing us with promotional services during the six months ended June 30, 2022. For the year ended December 31, 2021 and the six months ended June 30, 2022, the promotion services fees we incurred for top 10 third-party promoters were RMB42.6 million and RMB62.4 million, respectively. Usually, we entered into the promotion agreements with promoters for a term of one year. As Boyounuo® (BA1101) was launched in May 2021, the term of the promotion agreements in 2021 ranged generally from six months to seven months, which may be renewed annually. During the Track Record Period, the Group did not terminate the agreements with any promoters and there were no material breaches or deviations of the relevant agreements by promoters.

The following table sets forth the general key terms of the promotion agreements we entered into with third-party promoters:

Term:	As Boyounuo® (BA1101) was launched in May 2021, the term of the promotion agreements in 2021 is generally from six months to seven months, which may be renewed annually.
Designated promotion areas and exclusivity:	The agreements specify the relevant product (i.e., Boyounuo® (BA1101)) to be promoted and the geographic regions for which the third-party promoter is responsible. The agreements also prohibit third-party promoters from promoting our products outside of their respective designated promotion areas. In addition, our third-party promoters are not allowed to promote any other products with the same generic name of the relevant product, i.e., bevacizumab.
Promotion service scope:	The agreements set out the promotion service scope including promoting our product by visiting hospitals, organizing meetings and inviting experts with deep clinical experience to share knowhow or experience, organizing meetings and inviting leading healthcare experts to consult their views on product proposition and strategies and policy changes, collecting market intelligence, conducting business-supporting matters including tracking shipment, inventory verification and collecting accounts receivable, as well as the formulation and implementation of monthly promotion plans.

	We are required to provide product strategies, materials and any marketing support for the third-party promoters as well as provide training for the relevant staff of the third-party promoters. We evaluate the services provided by the third-party promoters and provide corrective advices for any violations of the third-party promoters from time to time. We are entitled to participate in any promotion activities organized by the third-party promoters. The third-party promoters are required to report to us for our consideration any target market conditions and changes. The third-party promoters should indemnify us for any of their violations of the agreement and laws and regulations in which case we may terminate the agreement.
Sales target and minimum sales requirement:	The promotion agreements set out the suggested quarterly sales targets for our third-party promoters. We do not grant any incentives or impose any penalties in connection with these sales targets. We do not stipulate any minimum sales requirements for our third-party promoters.
Promotion service fees:	We shall pay the promotion service fees to third-party promoters based on the prescribed fee ranges of different services to be provided.
Use of brand name and trademark:	Our third-party promoters are prohibited from using our name, brand name or trademark without prior our written consent.
Anti-corruption and anti-bribery obligations:	Third-party promoters are generally subject to anti-corruption and anti-bribery obligations, under which third-party promoters are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations. For more details, see "— Internal controls and risk management" in this section.
Confidentiality:	Third-party promoters have non-disclosure obligation, and undertake not to disclose our trade secrets or other business information to any third party without our prior written consent.
Termination:	We may terminate the promotion agreements in the event of, among others, (i) any material breach by our third-party promoters; or (ii) any other breach by our third-party promoters that is not remedied within a prescribed time-period.

The term of the promotion agreements between the third-party promoters and us is usually within one year, and we will review the validity of third-party promoters' licenses annually upon renewal of the agreements. As of the Latest Practicable Date, to our best knowledge, all third-party promoters had the relevant valid licenses to carry out promotion activities.

Our agreements with third-party promoters do not prohibit or restrict them from engaging sub-contractors based on their actual needs. Third-party promoters are entitled to sub-contract their obligations under the promotion agreements with the Company, and they are not required to obtain our consent. As a result, we are not in possession of the actual numbers of the sub-contractors engaged by the third-party promoters during the Track Record Period and up to the Latest Practicable Date.

During the Track Record Period and up to the Latest Practicable Date, we were not aware of any third-party promoters (including AstraZeneca China) having subcontracted their obligations to any distributors. All third-party promoters are Independent Third Parties of us and do not have any other relationships with us and our distributors as far as we are aware. Pursuant to our agreements with the third-party promoters, the third-party promoters remain ultimately responsible for their obligations under the agreements even if they engage any sub-contractors to perform their obligations. During the Track Record Period and as of the Latest Practicable Date, to our knowledge, none of the third-party promoters (including AstraZeneca China) has been the subject of any corruption, misappropriation and/or bribery charges in relation to their promotion activities within the scope of their collaboration with us. As confirmed by Frost & Sullivan and our PRC Legal Advisers, as third-party promoters (including AstraZeneca China) were not directly involved in drug sales during the Track Record Period and up to the Latest Practicable Date, our third-party promoter arrangements (including the arrangement with AstraZeneca China) do not contravene the requirements under the Two-Invoice System. Frost & Sullivan further confirmed that such arrangements are in line with latest industry practice.

Specifically, on May 26, 2021, we entered into an agreement with AstraZeneca China, as amended by a supplemental agreement dated March 7, 2022, to promote Boyounuo® (BA1101) in hospitals located in 657 counties over 12 provinces and autonomous regions in China, of which AstraZeneca China has an established sales and marketing network. Our in-house sales and marketing team focuses on municipalities and certain prefecture-level cities in 22 provinces and autonomous regions in China while other third-party promoters focus on provinces not otherwise covered by our in-house sales and marketing team and AstraZeneca China, such as Zhejiang, Fujian and Sichuan. AstraZeneca China is part of a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines. As of the Latest Practicable Date, AstraZeneca China was an Independent Third Party. The following table sets forth the key terms of our exclusive promotion agreement with AstraZeneca China:

Term:	Five years.
Designated promotion areas and exclusivity:	The agreement specifies the relevant product (i.e., Boyounuo® (BA1101)) to be promoted and the geographic regions for which AstraZeneca China is responsible, including 657 counties over 12 provinces and autonomous regions in China, including Inner Mongolia, Yunnan, Anhui, Guangxi, etc. The agreement also prohibits AstraZeneca China from promoting our products outside of the respective designated promotion areas. We are not allowed to engage any other promoters or let our in-house sales and marketing team to conduct any promotion within the designated promotion areas.
Promotion service scope:	The agreement sets out the promotion service scope, i.e., engaging in, organizing, sponsoring, or in any way conducting promotion activities targeted at medical professionals or any other channels of product promotion and sales including promoting our products by organizing academic promotion and visiting hospitals and introducing product information, such as the mechanisms of action and advantages of our products. We are responsible for the business management matters including business channel maintenance and management, negotiation with distributors and distributor management.

Subcontract:	AstraZeneca China is entitled to subcontract its obligations under the agreement to its related parties or any third party. However, AstraZeneca China remains responsible for its obligations under the agreement. AstraZeneca China must obtain our prior written consent before it subcontracts its obligations under the agreement to third parties. If AstraZeneca China subcontracts its obligations to its related parties, it only needs to report to us in writing in advance, and does not need to obtain our written consent. As of the Latest Practicable Date, to our knowledge, AstraZeneca China did not subcontract its obligations under the agreement to any parties.
Annual minimum sales requirement and annual baseline sales requirements:	The agreement sets out certain performance targets for AstraZeneca China to comply with, including annual minimum sales requirements and annual baseline sales requirements. On the one hand, if AstraZeneca China fails to meet the annual minimum sales requirements, the Group may terminate the agreement with AstraZeneca China. On the other hand, AstraZeneca China is entitled to receive promotion service fees based on the number of products promoted and sold, and an additional percentage bonus from 2022 on the number of products promoted and sold that exceed the annual baseline sales requirements, to further incentivize AstraZeneca China.
Mechanism of reviewing performance:	In order to review the performance of AstraZeneca China, on a monthly basis we would provide to AstraZeneca China a list detailing product distribution record in the areas in which it provides promotion services, and AstraZeneca China may review the list by visiting distributors and confirm the sales or financial record relating to our product with such distributors. In addition, we would provide quarterly statements of promotion service fees to determine the promotion service fees of AstraZeneca China. If there is a disagreement between AstraZeneca China and us in relation to the quarterly statements, it should be submitted to the committee (comprised of several representatives from AstraZeneca China and us) for discussion and determination.

To verify the amount of sales contributed by AstraZeneca China, we will obtain the relevant sales data of Boyounuo® (BA1101) related to hospitals within the designated promotion areas from a third-party distributors data integration ("**DDI**") service provider. The DDI service provider utilizes the DDI system to collect distribution data automatically from distributors. Most of our distributors currently install the DDI software provided by the DDI service provider to regularly upload the inventory and sales flow of Boyounuo® (BA1101) to the DDI system, and the DDI service provider will integrate and sort the data. We can check the inventory and sales data of Boyounuo® (BA1101) through the DDI system relating to those distributors who installed the DDI software.

During the Track Record Period and up to the Latest Practicable Date, there was no material discrepancy on the sales data between AstraZeneca China and us.

Consideration: AstraZeneca China receives promotion service fees based on the number of products promoted and sold. We receive business management fees based on the value of products sold but the fees will not be more than RMB2 million per year, which will be deducted from the promotion service fees paid to AstraZeneca China.

Use of trademark: AstraZeneca China is permitted to use trademark under certain circumstances.

Anti-corruption and anti-bribery obligations: AstraZeneca China is generally subject to anti-corruption and anti-bribery obligations pursuant to the terms of the agreement, under which AstraZeneca China is required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations. For more details, see "— Internal controls and risk management" in this section and "Risk Factors — Risks relating to our operations — Failure to comply with anti-corruption laws could subject us to investigations, sanctions or fines, which may harm our reputation and materially and adversely affect us".

Confidentiality: Both parties have non-disclosure obligations, and undertake to only use each other's trade secrets and other business information to the extent necessary and not to disclose such trade secrets or other business information to any third party.

Termination:	We may terminate the agreement in the event when, among others, (i) AstraZeneca China fails to meet the minimum sales requirements; or (ii) AstraZeneca China's non-compliance with laws results in products being blacklisted by regional governments, which is not remedied within a prescribed time-period. AstraZeneca China may terminate the agreement in the event when, among others, (i) we do not keep our registration permit valid; (ii) our products are recalled due to any serious adverse events caused by them; or (iii) our non-compliance with laws results in products being blacklisted by regional governments, which is not remedied within a prescribed time-period. Once Boyounuo® (BA1101) is included in the control list of centralized volume-based drug procurement schemes of China or any regional government in the designated promotion areas, the committee should discuss whether to terminate the agreement in whole or in part. If the committee fails to make a unanimous decision, this agreement will be terminated in whole automatically.

Frost & Sullivan confirmed that it is in line with the industry norm for promotion service fees to be tied directly to the sales of products, and the promotion fees paid to AstraZeneca China are in line with the industry norm.

In terms of Boyounuo® (BA1101), our marketing and promotion strategy generally is to (i) first gain sizable market share effectively by leveraging AstraZeneca China's established sales and marketing network in their designated areas (657 counties over 12 provinces and autonomous regions in China), (ii) focus on municipalities and certain prefecture-level cities in 22 provinces and autonomous regions in China within the reach of our in-house sales and marketing team, and (iii) capture any other regions not otherwise covered by the support from the other third-party promoters.

Because of the different strategic value brought by AstraZeneca China and the other third-party promoters, we entered into commercial arrangements of different terms and conditions with them respectively to achieve different objectives. For example, in order to gain sizable market share effectively and align mutual interests, (i) we granted AstraZeneca China the exclusive promotion rights in its designated regions; (ii) we structured AstraZeneca China's promotion service fee based on product sold and promoted and an additional percentage bonus on the number of products promoted and sold that exceed the annual baseline sales requirements, to further incentivize AstraZeneca China; (iii) we had a five-year long-term agreement with AstraZeneca China compared to the annually renewable term with the other third-party promoters; and (iv) we imposed annual minimum sales requirements failing which we may terminate the agreement. All these features are to closely align our product sales performance with AstraZeneca China's efforts and compensation. On the other hand, we do not have the

above arrangements with the other third-party promoters. Instead, we usually had one-year term agreements with those third-party promoters, without any minimum sales requirements, incentive bonus for meeting or penalties for not meeting sales target. This is mainly because we believe we may already gain a sizable market share through AstraZeneca China and our in-house sales and marketing team. We decided not to offer the costly promotion service fees based on product sold and promoted or offer any inflexible exclusive promotion right which may limit our marketing strategies in the future.

R&D partner and promoter

We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021 (the "**BA9101 Agreement**"), under which we granted OcuMension certain exclusive right to promote and commercialize BA9101 in China and OcuMension agreed to conduct the remaining Phase 3 clinical trial of BA9101 in China and bear the expense arising from the Phase 3 clinical trial. For more details of the Phase 3 clinical trial, see "— Our biosimilar portfolio — BA9101 aflibercept intraocular injection (a biosimilar to Eylea®) — Summary of clinical development history and results — Ongoing Phase 3 clinical trial" in this section. We reserve the full rights to develop, promote and commercialize BA9101 in overseas markets and will be the applicant of the overseas registration. OcuMension is a wholly-owned subsidiary of OcuMension Therapeutics, a China-based ophthalmic pharmaceutical platform company dedicated to identifying, developing and commercializing first- or best-in-class ophthalmic therapies and listed on the Stock Exchange (stock code: 1477). As of the Latest Practicable Date, OcuMension was an Independent Third Party. The following table sets forth the key terms of the agreement, as amended, with OcuMension:

Term:	The term ends on the tenth anniversary following the date of first delivery of BA9101 after marketing approval has been obtained.
Designated promotion areas and exclusivity:	OcuMension is responsible for the promotion of BA9101 in China. The agreement also prohibits OcuMension from promoting our products outside of China. We are not allowed to engage any other promoters to conduct any promotion of BA9101 in China. In addition, OcuMension is not allowed to promote, distribute and sell any other products that compete with BA9101 in China, which is with the same amino acid sequence as Eylea®.
Promotion service scope:	The promotion service scope includes promoting our products by visiting hospitals and disseminating product information, such as the mechanisms of action and advantages of our products.

Product distribution:	We shall appoint qualified distribution companies proposed by OcuMension. We shall not reject the qualified distribution companies proposed by OcuMension without good cause. We may also appoint OcuMension (if it obtained all relevant qualifications) directly for product distribution. If OcuMension becomes our distributor, we are not required to pay any promotion fees to it, and OcuMension is still obligated to make sales milestone payments and Annual Fees to us. We will discuss with OcuMension and conclude further details of key arrangements in such case by entering into separate agreements.
R&D, commercial production, commercialization authorizations and commercialization rights of BA9101:	We are responsible for conducting certain initial stages of the Phase 3 clinical trial, including selecting and deciding the research centers, passing the ethics committees and enrollment of some patients, and commercial production at our own costs as well as submitting the BLA of BA9101. OcuMension is responsible for completing the rest of Phase 3 clinical trial, including enrollment of the rest of patients and conducting the Phase 3 clinical trial, and promoting and commercializing BA9101 in China. All the clinical results and intellectual properties arising from the Phase 3 clinical trial are jointly owned by OcuMension and us. If we are benefited from utilizing such clinical results and intellectual properties outside of China, we are required to pay OcuMension 1% of the relevant overseas sales revenue as licensing fees and need to enter into a separate licensing arrangement with OcuMension, subject to the parties' negotiation, to govern further details of the arrangements. During the Phase 3 clinical trial, both parties shall attend monthly meetings, and OcuMension shall submit a written monthly work report to us. In addition, the clinical summary report must be confirmed in writing by us. Furthermore, both parties shall jointly form a committee with six members, three of which shall be designated by each party. The committee oversees the progress of the Phase 3 clinical trial. Moreover, we have the right to conduct random inspections of the Phase 3 clinical trial twice a year. If we have sufficient reasons to believe that there are issues that may lead to clinical trial failures or greater risks, we shall propose a solution to the committee. The solution will be mutually agreed upon by both parties.

We are responsible for submitting the BLA of BA9101 and OcuMension shall, in accordance with our requirements, provide us with all the necessary materials and information required for the BLA, actively cooperate with us in the BLA process, and accept clinical trial data verification by regulatory agencies in accordance with compliance requirements.

We are the title holder of the commercialization authorizations of BA9101 and shall continue to maintain and keep such authorizations effective. We may, at our sole discretion, transfer to OcuMension the titles of the said authorizations if OcuMension is qualified to hold such authorizations under the applicable laws and regulations and to the extent practicable, subject to a separate agreement to be entered into by us and OcuMension to effective the transfer.

We retain all global promotion and commercialization rights excluding China.

Assignment of rights: OcuMension is not allowed to assign any rights under this agreement to any third party without our prior written consent. However, OcuMension is allowed to assign its rights under the agreement to its related parties.

Forecasted sales volume: After the launch of BA9101, OcuMension should provide 12-month rolling forecasted sales volume at the end of every month, the first five-month forecasted sales volume of which should be binding, pursuant to which OcuMension should ensure designated distributors purchase our products to fulfil the relevant forecasted sales volume.

Consideration:

(a) Considerations payable by OcuMension:

(i) Upfront payment and milestone payments

OcuMension is obligated to pay the upfront payment of RMB15 million to us within 30 days upon signing of the agreement, and is obligated to make milestone payments to us upon achievement of certain development and regulatory milestones, including (i) RMB10 million upon the commencement of Phase 3 clinical trial; (ii) RMB10 million upon submission of the BLA for BA9101; and (iii) RMB30 million upon receipt of the BLA from the NMPA.

(ii) Sales milestone payments and Annual Fees

After BA9101 is approved for sale in China, OcuMension is obligated to make sales milestone payments to us, including (i) RMB10 million upon the annual net sales reaching RMB100 million for the first time; (ii) RMB20 million upon the annual net sales reaching RMB200 million for the first time; (iii) RMB50 million upon the annual net sales reaching RMB500 million for the first time; (iv) RMB100 million upon the annual net sales reaching RMB1 billion for the first time; and (v) RMB200 million upon the annual net sales reaching RMB2 billion for the first time. Besides, OcuMension agreed to pay 6% of the annual net sales (the "**Annual Fees**") to us.

Annual net sales are equal to the total annual sales of BA9101 less all applicable discounts, allowances, value added tax, and refunds due to product returns, exchanges and recalls resulting from distribution companies or OcuMension.

If two or more sales milestones are met in the same year, OcuMension is obligated to make the payment corresponding to each sales milestone, except for the sales milestone payment in previous years that has been paid to us.

(iii) Phase 3 clinical trial cost borne by OcuMension:

OcuMension should bear all expenses related to the Phase 3 clinical trial of BA9101 in China, except for production costs relating to clinical trial sample drugs.

As of the Latest Practicable Date, OcuMension has made the upfront payment of RMB15 million and milestone payments of RMB10 million to us.

During the course of Phase 3 clinical trial and up to June 30, 2022, the Company had incurred approximately RMB16.8 million on the expenses related to the Phase 3 clinical trial of BA9101 in China, which shall be fully reimbursed by OcuMension pursuant to the BA9101 Agreement.

(b) Consideration payable by us:

We agree to pay to OcuMension promotion service fees based on the number of products promoted and sold. The relevant formula based on which the promotion service fees payable to OcuMension are calculated is subtracting certain amount from the procurement unit price, and multiply it by net sales volume, where the procurement unit price represents the price that the distributors procure BA9101 from us.

(c) In terms of BA9101, we set forth the accounting treatment of the following items:

- We recognize our sales of the products as revenue;
- We recognize our commercial production cost as the principal component of cost of sales;
- We recognize promotion service fees payable to OcuMension as part of our selling and distribution expenses; and

- Considerations payable and borne by OcuMension (including upfront payment and milestone payments, sales milestone payments and the Annual Fees, as well as Phase 3 clinical trial cost borne by OcuMension) will be accounted as deduction items for promotion service fees payable to OcuMension under our selling and distribution expenses.

Use of trademark: We agree to use OcuMension's registered trademark on the outer packaging of BA9101.

Anti-corruption and anti-bribery obligations: OcuMension is generally subject to anti-corruption and anti-bribery obligations pursuant to the terms of the agreement, under which OcuMension is required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations. For more details, see "— Internal controls and risk management" in this section.

Confidentiality: Both parties have non-disclosure obligations, and undertake to only use each other's trade secrets and other business information to the extent necessary and not to disclose such trade secrets or other business information to any third party.

Termination: We may terminate the agreement in the event when, among others, (i) OcuMension promotes, distributes or sells any products that compete with BA9101, which is with the same amino acid sequence as Eylea®; (ii) OcuMension promotes BA9101 outside of China; or (iii) OcuMension fails to pay the upfront payment, milestone payments, sales milestone payments or expenses related to the Phase 3 clinical trial of BA9101 which is not remedied within a prescribed time-period.

	OcuMension may terminate the agreement in the event when, among others, (i) we engage other promoters to conduct promotion of BA9101 in China; (ii) we fail to supply OcuMension with the agreed quantity of products which is not remedied within a prescribed time-period; or (iii) we fail to pay the promotion service fees which is not remedied within a prescribed time-period. In the event of the above, in general we should return all relevant payments received from OcuMension with 6% compounded interest from the date of the payment (the "**Termination Payment**"). In the event of (i) and (iii), a penalty of double Termination Payment will apply to us.
Dispute resolution mechanism:	Any dispute arising from breach of this agreement shall be resolved through friendly negotiation by both parties. If the two parties cannot reach an agreement within 60 days after the dispute arises, either party has the right to submit the dispute to the Shanghai International Arbitration Center for arbitration in Shanghai in accordance with the arbitration rules in force at the time of the application for arbitration. The results of the arbitration is final and binding on both parties.

Our collocation arrangements with OcuMension on BA9101 and the split of responsibilities thereunder, driven by commercial considerations, aimed to maximize the benefits and mitigate potential risks of the development and commercialization of BA9101.

To enhance the sales performance of BA9101 in China, we identified OcuMension as a suitable R&D partner and promoter for a number of reasons. First, as a leading enterprise in terms of ophthalmic drugs, OcuMension is specialized in conducting the relevant clinical trials and accelerating the penetration in the China ophthalmology market. As of December 31, 2021, OcuMension had achieved a coverage of 1,024 hospitals nationwide according to its annual report of 2021. In addition, together with BA9101, OcuMension may build a portfolio of products in macular degeneration, building a broad pipeline in the treatment of back-of-the-eye diseases. In light of the above, BA9101's overall sales performance is expected to benefit from OcuMension's portfolio of ophthalmology products and its high hospital penetration in China. In addition, we are responsible for commercial production as both of us believe and agree that our strong CMC capability in both pilot and commercial scale production brings us higher efficiency and higher quality in manufacturing BA9101.

Thus, as a result of commercial negotiation, we granted OcuMension the exclusive rights to promote and commercialize BA9101 in China and as part of consideration OcuMension is required to conduct the remaining Phase 3 clinical trial of BA9101 in China and bear the expense arising from the Phase 3 clinical trial, and jointly owns the intellectual properties arising from the Phase 3 clinical trial in China with us. We remain the title holder of the commercialization authorizations of BA9101. We may, at our sole

discretion, transfer to OcuMension the titles of the said authorizations if OcuMension is qualified to hold such authorizations under the applicable laws and regulations and to the extent practicable, subject to a separate agreement to be entered into by us and OcuMension to effect the transfer, where OcuMension needs to pay additional consideration for such transfer. Such arrangements are to optimize our R&D resources allocation, enhance the efficiency of BA9101 R&D progress and expand the commercial value by leveraging on the expertise and competitive advantages of both parties. Both parties jointly benefit from such collaborations. As of the Latest Practicable Date, we did not have any plan to transfer the title of commercialization authorizations to OcuMension.

Frost & Sullivan confirmed that, typically, the division of R&D expenses is the result of mutual negotiation and decision between the involved parties and such practice of collective decision-making is common for biosimilars/ophthalmology drug candidates at such stage of development. Our Directors are of the view that the BA9101 Agreement has been entered into on normal commercial terms in light of the aforementioned split of responsibilities and comparable considerations received by the parties and on an arm's length basis.

As of the Latest Practicable Date, we did not have any material disputes with OcuMension in association with the BA9101 Agreement, and to the best of our knowledge, OcuMension intends to continue the cooperation and maintain close and stable relationship with us. As of the same date, to the knowledge of our Directors, pursuant to the BA9101 Agreement, OcuMension did not promote, distribute, sell or develop any biologics with the same amino acid sequence as Eylea®.

As of the Latest Practicable Date, we did not have any concrete plans to out-license pipeline assets in China or overseas.

Distributors

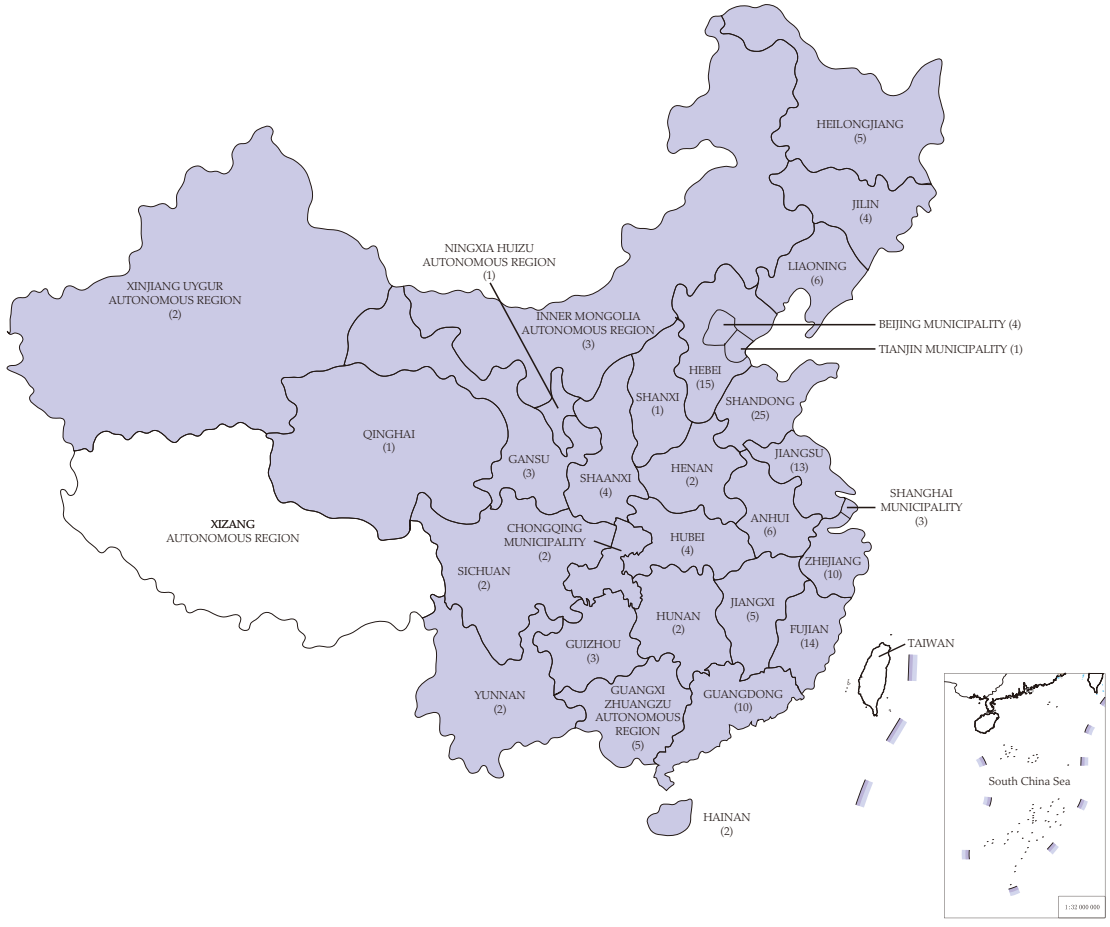
We sell our launched product, Boyounuo® (BA1101) to third-party distributors, and we derive all of our revenue from our sales to distributors. Our distributors are our direct customers, and are responsible for on-selling and delivering our products to hospitals. Our distributors are not authorized by us to use our trade name or any other material which may lead others to believe that they are acting on our behalf.

We benefit from our distributors' established distribution channels and local resources to save costs that would otherwise be required to establish and maintain a nationwide logistics network across the PRC on our own, and to increase the effectiveness of launching and selling our products in our target markets within a short period of time. We believe our distributorship model is in line with industry norm.

As of December 31, 2021 and as of June 30, 2022, we had an extensive distribution network of 138 and 160 distributors, respectively, penetrating selected regions and reaching more than 800 and more than 1,100 target hospitals and institutions in China, respectively. As of the Latest Practicable Date, our distribution network had covered 1,247 target hospitals and institutions in China. Among the 160 distributors as of June 30, 2022, compared to our distributors as of December 31, 2021, we had 18 new distributors and 142

pre-existing distributors who purchased from us during the six months ended June 30, 2022. Usually, we entered into the distribution agreements with distributors for a term of one year. As Boyounuo® (BA1101) was launched in May 2021, the term of the distribution agreements in 2021 is typically within one year, which may be renewed annually. During the Track Record Period, the Group did not terminate the agreements with any distributors. To the best knowledge of our Directors, during the Track Record Period, all of our distributors were Independent Third Parties, and none of our distributors were wholly-owned or majority controlled by our current or ex-employees. In addition, to the best knowledge of our Directors, there is no other relationship or arrangement (including family, business, financing, guarantee or otherwise in the past or present) between the distributors engaged by us during the Track Record Period and us.

The following map illustrates the geographical coverage of our distributors in the PRC as of June 30, 2022:



Terms of distribution agreements

We enter into standardized distribution agreements with our distributors. Individual sales contracts or purchase orders are generally separately entered into or placed for each purchase. The following table sets forth the key terms of our distribution agreements with distributors:

Term:	Typically within one year.
Designated distribution area and exclusivity:	The agreements specify the relevant products to be distributed and the geographic regions for which the distributors are responsible. The agreements also prohibit distributors from selling our products outside of their respective designated distribution area.
Sub-distributors:	Distributors are not allowed to engage sub-distributors within their designated distribution area without our prior written consent.
Sales target and minimum purchase requirement:	The agreements set out the estimated annual sales targets for our distributors. We do not grant any incentives or impose any penalties in connection with these sales targets. We do not stipulate any minimum purchase requirements for our distributors.
Pricing:	Our ex-factory prices to distributors are fixed during the term of the distribution agreements. In the event of an ex-factory price change as a result of market changes during the term of distribution agreement, we and the relevant distributor may negotiate price adjustments accordingly. We offer discounts to certain distributors in recognition of their payment to us on time. We also suggest to distributors the retail prices according to market conditions, but such price suggestions are not binding, and the distributors have the right to independently determine their retail price according to actual market demand.
Resale price management:	We generally do not control the prices at which our distributors resell our products to their customers.
Product flow reports:	Our distributors are required to provide us with a product flow report containing information including customers' information, monthly inventory level, monthly sales volume, monthly sales amount and batch numbers.

Return of products:	In line with the industry practice, we generally do not allow product returns or exchanges except for defective products, which is subject to approval by us. We generally do not accept the return of non-defective unsold or expired products.
Credit terms:	We generally grant our distributors credit terms of 30 to 90 days, with longer terms granted to selected distributors with whom we have built a strong business and financial track record. We also require prepayments for product deliveries to our distributors in certain instances from a credit control perspective.
Confidentiality:	Both parties have non-disclosure obligations, and undertake to only use each other's trade secrets and other business information to the extent necessary and not to disclose such trade secrets or other business information to any third party.
Renewal:	The agreements generally may be renewed or extended upon mutual agreement.
Termination:	We may terminate the distribution agreements in the event of, among others, (i) any material breach by our distributors, such as sales outside of their designated distribution areas; or (ii) any other breach by our distributors that is not remedied within a prescribed time-period.

We have a seller-buyer relationship with our distributors. We retain no ownership over the products that we sell to them, and all significant risks and rewards associated with these products are transferred to them upon delivery to and acceptance by them. Consequently, we recognize revenue from sales to our distributors upon delivery of our products to and acceptance by them. Our distributors on-sell our products to their customers, which do not have any contractual relationships with us and are not imposed with any of our control or oversight.

Distributor management

We select our distributors based on their proven distribution abilities, familiarity with their own target markets, financial strength, credit records and scale of operations. We require all our distributors to possess all licenses and permits necessary for the sales and distribution of pharmaceutical products. We require our distributors to adhere to the latest GSP standards for cold-chain storage and transportation so that they can deliver our products to covered hospitals in a safe and timely manner.

On December 26, 2016, the State Counsel Healthcare Reform Committee, National Health and Family Planning Commission, the NDRC and other relevant government authorities jointly issued the Circular on Issuing the Implementing Opinions on Carrying out the Two-Invoice System for Drug Procurement among Public Medical Institutions (for trial implementation) (關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)), aiming at eliminating the multi-tiered distribution of pharmaceutical products by allowing a maximum of two invoices between a manufacturer and a public medical institution and such system is currently applied to the sales of all pharmaceutical products to public medical institutions in all provinces, municipalities and autonomous regions in China. To comply with relevant regulations, we adopt the single-layer distribution model with distributors who directly on-sell our products to hospitals and pharmacies and require our distributors to get the consent from us when they need to carry out secondary distribution. To the best of our Director's knowledge, our Directors confirmed that during the Track Record Period and up to the Latest Practicable Date, there were no sub-distributors engaged in the distribution of our products. In light of the foregoing, as advised by our PRC Legal Advisers, our distributorship model has been in compliance with the Two-Invoice System during the Track Record Period and up to the Latest Practicable Date in all materials respects.

Where a distributor breaches the relevant distribution agreement, including non-compliance with applicable laws and regulations, we will give the distributor a notice and require rectification. If no remedial action is taken within a prescribed time period, we will have the right to terminate the relevant distribution agreement. During the Track Record Period, we did not terminate our business relationship with any distributors based on their breach of their distribution agreements or their non-compliance with regulatory requirements.

Prevention of cannibalization

In order to manage the risk of cannibalization of sales among our distributors, we have adopted the following measures:

- Geographic restrictions. We specify the designated distribution area for which our distributors are responsible in our distribution agreements with them. The agreements also prohibit distributors from selling our products outside their respective designated distribution areas without our prior written consent. To our knowledge, our distributors generally do not sell our products to the same hospitals or institutions.

- End customer monitoring. If needed, we can consult with the distributors to acquire the information including quantities of products sold, product retail price, inventory level, etc.

- Accountability policy. For any unauthorized sales outside the designated distribution areas, we may penalize the relevant distributors according to the terms of our distribution agreements with them, including a penalty of 1.5 times the bid price multiplied by the quantity of the products sold outside the designated distribution areas and the termination of relevant distribution agreements.

During the Track Record Period and up to the Latest Practicable Date, we were not aware of any material cannibalization or competition among our distributors within the same geographical area. Our Directors are of the view that the above measures are sufficient to mitigate potential cannibalization and competition among distributors.

Inventory management and control

We have implemented the following policies and measures, which, combined with our product return policies and the independence of our distributors, help ensure that our sales to distributors reflect genuine market demand and mitigate the risk of inventory accumulation in the distribution channels.

We generally grant our distributors credit terms of 30 to 90 days, and typically only grant longer credit terms to major distributors on a case-by-case basis based on our assessment. We believe that the short credit term requires our distributors to effectively manage their cash flow and ensure that procurements are made based on actual demand. This is particularly effective for our small-to medium-scale distributors, which we believe generally have more limited capital resources.

In addition, we require distributors to provide us with product flow reports containing information including customers' information, monthly inventory level, monthly sales volume, monthly sales amount and batch numbers. In general, we review and evaluate these data of our distributors on a monthly basis to enable us to make periodic assessments of actual market demand for our products and analyze the inventory levels of our distributors. We actively adjust our sales strategy and geographic or product coverage of each distributor based on market demand and each distributor's capacity.During the Track Record Period and up to the Latest Practicable Date, we did not notice any unusually large procurements that were inconsistent with distributors' past practices, nor did we notice any abnormally high inventory level of our distributors.

Anti-corruption and anti-bribery measures

Distributors are generally subject to anti-corruption and anti-bribery obligations pursuant to the terms of our distribution agreements, under which distributors are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations. For more details, see "— Internal controls and risk management" in this section.

During the Track Record Period and as of the Latest Practicable Date to our knowledge, none of the distributors has been the subject of any corruption, misappropriation and/or bribery charges in relation to their distribution activities of our products.

During the Track Record Period and up to the Latest Practicable Date, we did not provide financing to any of our distributors except for credit terms we granted to them under the relevant distribution agreements. There were no material product returns from our distributors during the Track Record Period. For more details, see "— Product returns and warranties" in this section.

Logistics arrangement

We generally use third-party logistics service providers to transport our products to our distributors in the PRC. We have entered into logistics service agreements with these providers, pursuant to which they are responsible for any loss caused by their negligence during the course of their logistics services, including transfer, loading, unloading, transportation and delivery to our customers.

Pricing

We believe an optimal pricing strategy is the key to develop and maintain our long-term competitiveness. On the one hand, biopharmaceutical companies, like us, need to compete in various aspects, including pricing, in order to gain market share due to the strong competition in the industry. On the other hand, in order to achieve a sustainable development, biopharmaceutical companies including us also need to maintain a reasonable profit level so they can recoup their investment costs. As advised by Frost & Sullivan, in general the price of biosimilar can commensurate with its investment cost. Striking a balance between maintaining competitive price and a reasonable profit level via an optimal pricing strategy becomes an important task for biopharmaceutical companies.

In terms of our pricing strategies for biosimilar products, we generally plan to price our biosimilar products upon their launch lower than their reference drugs to gain market share initially, and benchmark our price based on other competing biosimilar products. The price of our biosimilar product generally is in line with that of other competing biosimilar products. According to the Frost & Sullivan Report, globally, biosimilars are generally 10%–37% cheaper than their reference drugs. Take bevacizumab as an example, the average price of biosimilars based on available information is approximately 24% lower than the reference drug in the United States. We also determine our product pricing after taking into account a series of factors such as demand for our products regulatory requirements and the affordability and accessibility of reference drugs. Nonetheless, in the short- to medium-term, we may not necessarily adjust our prices of biosimilar products to benchmark other competing products in all cases as we believe our competitive advantages should lie in our brand name, reputation and after-sale services which will distinguish us from our competitors. In light of the industry trend of lowering market prices of biosimilars in China and overseas, we will continue to focus on our R&D, CMC, brand name, reputation and after-sale services to make us less reliant on pricing to compete. In the meantime, our another competitive advantage is becoming the first- or early-mover in drug development to occupy market share ahead of other competitors in China, which generally is less susceptible to price competition from competitors falling behind on their product launch.

In addition, usually reference drugs are already included in the NRDL and its biosimilars are automatically included in the NRDL except that drug payment codes will need to be separately applied for and registered with each of the provinces, autonomous regions and municipalities in China to become eligible for local medical insurance. We will apply for the payment codes for all our biosimilar products upon their launch so they will be eligible for local medical insurance. Most of the reference drugs of our biosimilar drug candidates have been included in the NRDL. We anticipate that all of our biosimilar drug candidates can be included in the NRDL and we can successfully apply for their payment codes so they can become eligible for local medical insurance after their launch.

Furthermore, as a part of our strategy of affordable innovation, we aim to carefully control costs throughout our raw material procurement optimization, research, development and manufacturing processes. For more details of our measures to control costs, see "— Manufacturing" in this section. We regularly evaluate product gross profit margin and will continuously monitor market prices as more biosimilars enter the market as well as various developments as they occur, and in turn may adjust our pricing for Boyounuo® (BA1101) as appropriate.

In terms of our pricing strategies for innovative drug candidates, we plan to determine the pricing based on the value of clinical treatment, such as the current treatment cost of disease remission and cure, as well as the price skimming strategy upon their launch. Usually, pharmaceutical companies first adopt price skimming strategy to innovative drugs to facilitate early recovery of their research and development costs, and reduce prices to maintain or increase their market share when competing products appear in the market at a later stage. In addition, innovative drugs included in any national medical insurance negotiation list generally need to undergo a pricing negotiation process with the PRC government, which may result in a decrease in its retail price across the country. The average price cut is approximately 60%. A bidding process is required for innovative drugs to be included in the NRDL and the review is based on various factors such as clinical need and utilization, reasonable pricing, cost-effectiveness, etc. We will apply to include the innovative drug candidates in the NRDL upon their launch. We anticipate that all of our innovative drug candidates can be included in the NRDL after their launch. According to the Frost & Sullivan Report, it takes 14 months in 2021 and 29 months in 2020 for innovative drugs to be included in the NRDL.

Furthermore, centralized procurement in China has strong bargaining power over pricing of biopharmaceutical products. See "Risk Factors — Risks relating to the commercialization of our drug candidates — Even if we are able to commercialize any drug candidates, the drugs may become subject to national or other third-party reimbursement practices, healthcare reform initiatives or unfavorable pricing regulations, which could harm our business" for further details.

Product returns and warranties

We generally do not accept any product returns, except for defective products. For defective products, we are fully responsible for the cost of return and replacement of these products. In respect of the return policy with our distributors, see "— Commercialization, sales, marketing and distribution — Distributors — Terms of distribution agreements" in this section for more details.

We receive feedback from our distributors and end customers. We have dedicated personnel who are responsible for taking complaint calls and regularly review and analyze the feedback received. We treat such feedback and complaints seriously. We have implemented detailed procedures on how to handle quality complaints and provide for the contingency for any adverse patient reaction to our products. Our pharmacovigilance and quality assurance specialists are responsible for following up customer complaints to ensure that they have been dealt with appropriately.

We did not provide any warranties on our products and did not have any provisions for warranty claims during the Track Record Period. During the Track Record Period and up to the Latest Practicable Date, the amounts of our product returns and exchanges were insignificant. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material complaint or product liability or other legal claims from our customers due to problems associated with the quality of our products.

We have also established product recall procedures with reference to relevant requirements, including GMP, and have prescribed recall guidelines and processes, which specify responsible persons to notify upon a recall and the handling procedure of the recalled products. During the Track Record Period and up to the Latest Practicable Date, we did not have any product recall due to quality problems.

CUSTOMERS

In 2021 and for the six months ended June 30, 2022, we derived all of our revenue from the sales of Boyounuo® (BA1101) in China. We did not record any revenue in 2020.

For the six months ended June 30, 2022, all of our five largest customers were distributors and the aggregate sales to our five largest customers were RMB172.8 million, representing 78.3% of our revenue. Sales to our largest customer for the same period were RMB90.0 million, representing 40.8% of our revenue. For 2021, all of our five largest customers were distributors and the aggregate sales to our five largest customers were RMB129.9 million, representing 81.8% of our revenue. Sales to our largest customer for the same periods were RMB48.3 million, representing 30.4% of our revenue. The following is a summary of the sales to our five largest customers for the periods indicated:

Five largest customers for the year ended December 31, 2021	Commencement of business relationship	Company background	Credit terms	Sales amount	Percentage of revenue
				RMB'000	
Customer A	2021	A company primarily engaging in pharmaceutical R&D, manufacturing, distribution, retail and pharmaceutical logistics	15–110 days	48,291	30.4%
Customer B	2021	A company primarily engaging in the distribution of medical devices and drugs	70 days	32,852	20.7%
Customer C	2021	A company primarily engaging in pharmaceutical R&D, manufacturing, distribution and retail	30–90 days	28,223	17.8%

Five largest customers for the year ended December 31, 2021	Commencement of business relationship	Company background	Credit terms	Sales amount	Percentage of revenue
				RMB'000	
Customer D	2021	A company primarily engaging in pharmaceutical commodity marketing, logistics and distribution and the provision of pharmaceutical supply chain solution services	30–90 days	13,161	8.3%
Customer E	2021	A company primarily engaging in pharmaceutical R&D, manufacturing, wholesale and retail, pharmaceutical e-commerce and pharmaceutical logistics	45 days	7,368	4.6%
Total				129,895	81.8%

Five largest customers for the six months ended June 30, 2022	Commencement of business relationship	Company background	Credit terms	Sales amount	Percentage of revenue
				RMB'000	
Customer A	2021	A company primarily engaging in pharmaceutical R&D, manufacturing, distribution, retail and pharmaceutical logistics	15–100 days	90,018	40.8%
Customer C	2021	A company primarily engaging in pharmaceutical R&D, manufacturing, distribution and retail	30–90 days	37,078	16.8%
Customer D	2021	A company primarily engaging in pharmaceutical commodity marketing, logistics and distribution and the provision of pharmaceutical supply chain solution services	30–90 days	28,306	12.8%
Customer F	2021	A company primarily engaging in pharmaceutical distribution, manufacturing of medical devices and investment of pharmaceutical industry	45–90 days	9,226	4.2%
Customer G	2021	A company primarily engaging in rental of medical device, wholesale and retail of medicine and other products	50–65 days	8,127	3.7%
Total				172,755	78.3%

All of our five largest customers during the Track Record Period are Independent Third Parties. During the Track Record Period, none of our Directors or any Shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following the completion of the [**REDACTED**] (but without taking into account the exercise of the [**REDACTED**]) nor any of their respective associates had any interest in any of our five largest customers.

RAW MATERIALS AND SUPPLIERS

Raw materials and inventory management

Our main raw materials used in the production process for drug candidates and drugs include glucose, polysorbate, reagents, cell culture media, chromatography resins, excipients, packaging materials and consumables, such as single-use bioreactors and buffer preparation bags. We purchased these raw materials and supplies from a variety of suppliers in China and globally, including the United States, Germany, Switzerland, the United Kingdom and Japan. We had also engaged service providers such as CROs and CDMOs primarily to support our clinical trials and to produce our drug candidates. For further details, see "— Research and development — Engagement of third parties in research and development" in this section. We also engage promoters to help us publicize and maximize market potential of our products. For further details, see "— Commercialization, sales, marketing and distribution — Third-party promoters" in this section.

We operate a warehouse at our Yantai Site, with full-time staff responsible for the inspection, storage and distribution. The warehouse accommodates different storage conditions, such as temperature and humidity. We have a comprehensive warehousing management system for raw materials, consumables and finished products that meets GMP requirements, including an integrated digital warehouse management system for inventory management which can dynamically monitor and manage raw materials. We monitor the quality of supplies according to our standard operating procedure. We also conduct sampling inspection of raw materials before they are used in trial production.

We are constructing fully automated warehouses covering an area of approximately 2,331 square meters in the Yantai Site, which are expected to be completed by November 2022. To meet the different needs of storage, the warehouses under construction will be divided into cold storage, normal temperature storage, shady storage, packaging material preparation room, tally area, cold storage in and out area, drug substance storage room, waste room, unqualified product storage, labor protection supplies storage, spare warehouse, etc.

We generally maintain an inventory level for raw materials at the warehouse to support production needs. We typically place orders one year in advance in order to take into account the time needed for the suppliers to manufacture the product, conduct quality testing and arrange transportation (along with any customs approvals needed), as well as for us to conduct internal inspections and testing of the product upon arrival. We believe the raw materials we require are readily available from a number of reputable suppliers and we in general do not rely on any particular supplier.

As of June 30, 2022, our inventories which mainly include raw materials and consumables amounted to RMB140.9 million. The following table sets forth the breakdown of our inventories and their respective remaining shelf life by categories as of June 30, 2022.

Category of inventories	Shelf life
Consumables	one month – 9.5 years
Reagents	four months – 4.5 years
Packaging materials	six months – five years
Cell culture media	one month – 2.5 years
Chromatography resins	3.5 years – 4.5 years
Polysorbate	eight months – 1.5 years
Glucose	1.5 years – 2.5 years
Others	one month – 4 years

Supply chain management and key suppliers

Our supply chain management team has the following four functions: (i) business planning, which is to develop our demand and supply planning, and to establish our matter production schedule and raw materials planning; (ii) procurement, which is to procure equipment and materials needed for our pre-clinical studies, clinical trials and manufacturing; (iii) supply chain operation, which is to import, transport and warehouse raw materials; and (iv) supply chain optimization, which is to optimize our supply chain operation and management. As of June 30, 2022, our supply chain management department had seven personnel, and we expect this number to grow as we expand our operations.

We adopt either direct or indirect procurement, and both follow a set of standard operating procedures. For direct procurement, we purchase directly from suppliers selected from our database of GMP certified suppliers. For indirect procurement, we undertake a tender process to select the agent or intermediary from whom we then make a purchase. In addition to materials used, we also require various services including logistics and transportation, warehousing and cold chain storage in our clinical trials and production. We currently obtain logistics services primarily from some of the largest pharmaceutical distribution companies in the PRC.

In selecting our suppliers, we focus on identifying and forming relationships with reputable manufacturers with strong quality control measures and an excellent compliance track record, while also taking into consideration cost factors such as logistics. We have historically primarily relied on imported supplies from well-known, international brands. Going forward, we may consider working with PRC enterprises which have a track record of strong product integrity and which meet our quality guarantee requirements.

For the six months ended June 30, 2022, purchases from our five largest suppliers in aggregate accounted for 21.9% of our total purchases, and purchases from our largest supplier accounted for 6.2% of our total purchases for the same period, respectively. For

the years ended December 31, 2020 and 2021, purchases from our five largest suppliers in aggregate accounted for 28.9% and 19.7% of our total purchases, respectively, and purchases from our largest supplier accounted for 7.4% and 5.4% of our total purchases for the same periods, respectively. The following is a summary of the purchases from our five largest suppliers for the periods indicated:

Five largest suppliers for the year ended December 31, 2020	Commencement of business relationship	Background	Purchases	Credit terms	Purchase amount	Percentage of total purchase
					RMB'000	
Supplier A	2015	A research institution primarily engaging in pre-clinical safety evaluation and efficacy evaluation of new drugs	R&D services	7–10 days	19,342	7.4%
Supplier B	2018	A manufacturer and distributor of chemical reagents, experimental consumables, instruments and equipment and other products	Materials	30 days	17,395	6.6%
Supplier C	2015	An R&D service provider primarily engaging in development and production of biopharmaceuticals	R&D services	10–30 days	16,455	6.3%
Supplier D	2017	A CRO	R&D services	30 days	11,415	4.4%
Supplier E	2016	A company primarily engaging in the sale of biological products	Materials	90 days	11,043	4.2%
Total					75,650	28.9%

Five largest suppliers for the year ended December 31, 2021	Commencement of business relationship	Background	Purchases	Credit terms	Purchase amount	Percentage of total purchase
					RMB'000	
Supplier F	2017	A company primarily engaging in domestic distribution and production of life science products	Materials	90 days	24,765	5.4%
Supplier D	2017	A CRO	R&D services	30 days	19,915	4.3%
Supplier G	2021	A company primarily engaging in providing marketing and promotion services for pharmaceutical companies	Promotion service	15 days	16,472	3.6%
Supplier C	2015	An R&D service provider primarily engaging in development and production of biopharmaceuticals	R&D services	10–30 days	16,258	3.5%
Supplier A	2015	A research institution primarily engaging in pre-clinical safety evaluation and efficacy evaluation of new drugs	R&D services	7–10 days	13,175	2.9%
Total					90,585	19.7%

Five largest suppliers for the six months ended June 30, 2022	Commencement of business relationship	Background	Purchases	Credit terms	Purchase amount	Percentage of total purchase
					RMB'000	
Supplier H	2020	A company primarily engaging in the management of medical devices, electromechanical equipment and laboratory instruments and components as well as providing technical services	Equipment	10-90 days	22,894	6.2%
Supplier F	2017	A company primarily engaging in domestic distribution and production of life science products	Materials	90 days	15,227	4.1%
Supplier I	2014	A company primarily engaging in biotechnology research and development	Materials	30 days	14,904	4.1%
Supplier J	2021	A company primarily engaging in providing marketing and promotion services for pharmaceutical companies	Promotion service	15 days	14,482	3.9%
Supplier K	2020	A company primarily engaging in providing preclinical research services for global biopharmaceutical and medical device company	R&D	10 days	13,138	3.6%
Total					80,645	21.9%

All of our five largest suppliers during the Track Record Period are Independent Third Parties. During the Track Record Period, none of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [**REDACTED**] (but without taking into account the exercise of the [**REDACTED**]) nor any of their respective associates had any interest in any of our five largest suppliers.

EMPLOYEES

As of June 30, 2022, we had 631 employees. Due to the high technical requirements of our industry, our workforce comprises many high calibre scientists and experts with extensive experience and pedigree in the biopharmaceutical industry. Most of our workforce is highly-educated, with many employees holding advanced degrees from overseas institutions. The table below sets out a breakdown of our employees by the level of education:

Level of education	**Number of employees**
Ph.D. or equivalent	14
Master's degree or equivalent	201
Bachelor's degree or equivalent	200
Others	216
Total	**631**

Our employees with Ph.D, Master's degrees or equivalent degrees have backgrounds in biotechnology, biology, chemistry, chemical engineering or other relevant fields. As of June 30, 2022, our core team comprised 68 industry experts. They bring robust technical and project execution knowledge from their prior working experience at other pharmaceutical companies. Many of our key research and development and management team members also possess Master's degrees in business administration. This strong talent pool allows us to effectively carry out drug discovery and research and development and successfully execute our strategies of offering affordable and innovative medicines.

The table below sets forth, as of June 30, 2022, a breakdown of our employees by function across all jurisdictions:

Function	Number of employees
Sales and marketing and administrative	73
Research and development	253
Manufacturing and quality management	305
Total	**631**

Substantially all of our employees undergo on-site training for a period from weeks to a couple of months prior to becoming full-time members of our workforce. Our training focuses on operational skills, regulatory compliance and production processes. We emphasize on-the-job training as a constant, ongoing objective for our employees. All employees also participate in formal training on an annual basis, where we focus on the latest technical developments and updates in regulatory requirements.

Recruiting and maintaining a team of talented professionals is one of our key strategies and long-term focus. We recruit our employees primarily through recruitment websites, internal referrals and job fairs at universities and industry conferences. We do not typically hire recruiting agents for our hiring needs. Our candidate selection process emphasizes factors such as talent, sound technical skills, academic performance and professional experience, strong integrity and ethics, dedication to medical and pharmaceutical research as a career and fitness within our corporate culture. We generally enter into individual employment contracts with our employees setting out arrangements of compensation and insurance, grounds for termination and confidentiality. Employment contracts with our R&D personnel also typically contain a non-competition clause. We also provide benefits to our employees as part of their compensation package which we believe is in line with industry norm. For example, our PRC-based employees are entitled to social insurance as mandated by the PRC Social Insurance Law, including pension, basic medical insurance, maternity insurance, work-related injury insurance, unemployment insurance and housing provident fund. To stay competitive in the market for talent, we have also adopted share incentive plan to incentivize our employees. See "History, Development and Corporate Structure — Our Corporate Developments — Our Company — Establishment of employee share incentive plan" for further details.

Going forward, we plan to ramp up hiring in line with our development progress. In particular, as we continue to commercialize our existing product, progress the development of our drug candidates, commercialize such candidates for marketing and sale, expand our product pipeline and ramp up our production capability (most notably in connection with the Yantai Site which we expect to significantly increase our manufacturing capacity), we will need to recruit and maintain an increasingly large workforce of qualified personnel. Given the strong competition for high-quality talent in our industry, we plan to expand our hiring resources and industry outreach accordingly. See "Risk Factors — Risks relating to our operations — Our success depends on our ability to attract, train, motivate and retain highly skilled scientists and other technical personnel" for further details.

As of the Latest Practicable Date, our employees were represented by a labor union. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes, work stoppages, labor disputes or other actions which had a material adverse effect on our business and operations.

COMPETITION AND COMPETITIVE LANDSCAPE

The regional and global biologics industries, and the pharmaceutical industry generally, are highly competitive, with a large number of well-known multinational companies, regionally-strong players and companies in the pre-product commercialization phase. Many of our prospective competitors may have significant resources and brand awareness, and may be deeply entrenched in certain market segments, whether by geographic region or by drug type. These competitors may capture significant first-entrant advantages in establishing market presence and brand awareness and adversely affect the market of our biosimilar products in light of the Prescription Management Regulation that requires a hospital to only procure the reference drug and one biosimilar for each generic drug. For further details, see "Risk Factors — Risks relating to the commercialization of our drug candidates — Certain of our biosimilar products may not be as advanced in development as some of the equivalent biosimilar candidates being developed by our competitors, which may result in our competitors capturing significant first-entrant advantages with respect to their products".

With respect to our biosimilar candidates, we expect to compete based on our well-established and proven commercialization capability backed by marketing strategies implemented by dedicated marketing teams and our ability to produce drugs that are of similar quality and efficacy as the relevant reference drugs at lower costs. With respect to original or innovative drug candidates, we expect to compete primarily based on our ability to identify and address new or underserved treatment needs, whether due to a lack of existing drugs generally or as a result of such drugs being unavailable or unaffordable in certain regional markets (in which case making such drug candidates available at affordable prices would also be a key competitive factor). We believe that both types of drug candidates offer significant untapped market opportunities both in China and abroad. At the same time, we expect to face significant competition from domestic and international pharmaceutical companies. However, we expect our major competitors to be other biotech companies in China and elsewhere that focus on producing biologics whose reference drugs may be unavailable, unaffordable or non-existent. For more details, see "— Our biosimilar portfolio — Our Commercialized Product: Boyounuo® (BA1101) bevacizumab injection (a biosimilar to Avastin®) — Market opportunities and competition", "— Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®) — Potential market opportunities and competition", "— Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®) — Potential market opportunities and competition", "— Our biosimilar portfolio — BA9101 aflibercept intraocular injection (a biosimilar to Eylea®) — Potential market opportunities and competition", "— Our biosimilar portfolio — BA1104 (a biosimilar to Opdivo®) — Potential market opportunities and competition", "— Our biosimilar portfolio — BA5101 (a biosimilar to Trulicity®) — Potential market opportunities and competition", "— Our innovative antibody portfolio — Our Core

Product: LY-CovMab — Potential market opportunities and competition", "— Our innovative antibody portfolio — BA1105 — Potential market opportunities and competition" and "— Our innovative antibody portfolio — BA1201 — Potential market opportunities and competition".

AWARDS AND RECOGNITIONS

We have received various awards and recognitions which reflect the high esteem under which we are held and our renowned industry achievements, including Yantai Engineering Laboratory Development of Human Monoclonal antibody new biological agents (煙台市全人單抗與新型生物製劑開發工程實驗室) by Yantai Development and Reform Commission (煙台市發展和改革委員會) in 2018, New R&D Institutions of Shandong Province (山東省新型研發機構) by Department of Science & Technology of Shandong Province (山東省科學技術廳) in 2020, Yantai Enterprise Technology Center (煙台市企業技術中心) by Yantai Development and Reform Commission (煙台市發展和改革委員會) in 2021 and Top 300 of 2021 Venture 50 (2021 Venture 50 "風雲榜" 300 強) by 2021 Venture 50 Committee in 2021. We were ranked 7th in Top 100 Innovative Biomedicine Companies by 2022 Future Healthcare VB100 in 2022.

LAND AND PROPERTIES

We own our Yantai Site which has a total GFA of approximately 33,504.1 sq.m. located in the Hi-tech Industrial Development Zone in Yantai (煙台高新區), Shandong province. For further details, see "— Manufacturing" in this section.

In addition, we leased five properties with an aggregate GFA of approximately 9,783.2 sq.m in the PRC and two properties with an aggregate GFA of approximately 1,216.6 sq.m in the United States. We believe our current leased properties are sufficient to meet our near-term needs, and additional or alternative space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration or in obtaining alternative space suitable for our future needs.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

Location	Type of property	Address	GFA	Lease term	Expiry dates
			(sq.m)		
Yantai, Shandong province, the PRC	Office and R&D	The north side of the third floor, the north side of the fifth floor and the corridor in building no. 4 and no. 5 in the Shandong International Biotechnology Park, Yantai City, Shandong Province, the PRC	4,900.0	One year	December 31, 2022
Yantai, Shandong province, the PRC	R&D	The east side of 8F in building no. 6 in the Shandong International Biotechnology Park, Yantai City, Shandong Province, the PRC	690.0	One year	December 31, 2022
Yantai, Shandong province, the PRC	Warehouse	Part of 2/F, Building 28 in Luye Pharmaceutical Industrial Park in Yantai, Yantai City, Shandong Province, the PRC	1,173.0	One year	July 31, 2023
Yantai, Shandong province, the PRC	Office	4F of building no. 1 in the Shandong International Biotechnology Park, Yantai City, Shandong Province, the PRC	1,412.2	One year	December 31, 2022

Location	Type of property	Address	GFA	Lease term	Expiry dates
			(sq.m)		
Nanjing, Jiangsu province, the PRC	Office and laboratory	2F of Comprehensive Building and 1F of Research Building, 28 Gaoxin Road, and storage racks in Preparation Building, 28 Gaoxin Road, and test rooms in Quality Control Building in 121 Huakang Road, Gaoxin District, Nanjing, the PRC	1,608.0	One year	August 31, 2023
Boston, Commonwealth of Massachusetts, the United States	Office and laboratory	Suite 304 and Suite 100E, 19 Presidential Way, Woburn, MA 01801, the United States	1,216.6	Two years	December 31, 2022

As of the Latest Practicable Date, except for the leased property in Nanjing, all of our lease agreements for properties in China had not been registered with relevant authorities in China. Our PRC Legal Adviser is of the view that the non-registration of lease agreements will not affect the validity of the lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000 for each of these leasing properties. For further details, see "Risk Factors — Risks relating to our operations — We may face penalties for the non-registration of our lease agreements in China".

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of June 30, 2022. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 38(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our Group's interests in land or buildings.

INSURANCE

We believe our insurance coverage is in line with the industry norm in the jurisdictions where we operate, such as insurance covering adverse events in clinical trials for our Core Products and Commercialized Product, product liability insurance relating to the use of our biologics and property loss insurance. In addition to the product liability insurance we already procured for Boyounuo® (BA1101), we also plan to procure product liability insurance to address any potential product liability claims from third parties after the commercialization of our product candidates, e.g., BA1102, BA6101 and BA9101. However, our insurance may be insufficient to cover all claims for product liability or damage to our fixed assets. See "Risk Factors — Risks relating to our operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources" for further details.

INTERNAL CONTROLS AND RISK MANAGEMENT

It is the responsibility of our Board to ensure that we maintain sound and effective internal controls to safeguard our Shareholders' investment and our assets at all times. We have adopted, or expect to adopt before the [**REDACTED**], a series of risk management and internal control policies, procedures and programs designed to provide reasonable assurance for achieving objectives, including effective and efficient operations, reliable financial reporting and compliance with applicable laws and regulations. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

We have engaged an independent internal control consultant to assess and provide remedial advice on, our internal control and risk management. Based on the findings identified by the internal control consultant, we have made improvements and remedied all internal control risks and deficiencies identified by internal control consultant. As of the Latest Practicable Date, there was no outstanding material issue relating to our internal control systems. Therefore, our Directors are of the view that our current internal control measures are sufficient and effective in all material respects.

Anti-bribery and anti-corruption

In particular, we have established a code of conduct and ethics governing commercial transactions (the "**Code of Conduct**"). Specifically, the Code of Conduct prescribes that providing or accepting appropriate gifts and hospitalities are customary business practices which are considered business etiquette during the establishment of relationships with our business partners, to the extent that such gifts and hospitalities will not affect or appear to affect the fairness of commercial decisions. All political contributions, whether directly or through professional associations, are strictly prohibited unless otherwise approved by our Board of Directors. In addition, the Code of Conduct strictly prohibits provision or acceptance of kickbacks, bribes or other improper gains or benefits by our employees. Our employees are required to sign a declaration confirming that they have received, read and understood the Code of Conduct and

undertake their compliance with the Code of Conduct requirements. Employees who violate the Code of Conduct are subject to penalties, including termination of employment.

To further enhance our anti-bribery and anti-corruption practice, we also adopted a set of internal policies against bribery and corrupt activities (the "**Internal Anti-bribery Policies**"), which strictly prohibit all employees and other personnel acting on behalf of us from making, proposing or promising improper payments, directly or indirectly, in any form of cash, physical assets, loans, gifts, luxury trips, entertainments, donations, other valuables or benefits to anyone, including government officers, for the purposes of acquiring or securing any business or improper advantage, regardless of whether we benefit from such improper payments. Specifically, all employees are prohibited from (i) the offer of cash or cash equivalents to government officers; (ii) the offer of personal gifts (except for small amounts of gifts in accordance with customary business practice) to government officers; (iii) reimbursement of travel and accommodation expenses for accompanying guests and relatives of government officers; and (iv) the offer of entertainment or leisure activities to government officers (other than conference-related accommodation). All charitable donations are required to be made in accordance with the Internal Anti-bribery Policies. In general, the Internal Anti-bribery Policies strictly prohibit facilitation payments, regardless of its legality in the relevant jurisdictions. Employees who violate the Internal Anti-bribery Policies are subject to penalties, including termination of employment. Such policies, measures and procedures are also designed to ensure that we and our researchers, sales and marketing personnel and other staff comply with anti-bribery and anti-corruption laws with respect to interactions with CDMOs and CMOs, sales and marketing, drug research and development and patient and customer interactions. The Internal Anti-bribery Policies also include whistleblower provisions that require all employees to report any suspected non-compliance.

We have formed the Audit Committee comprising two independent non-executive Directors and one non-executive Director as part of our measures to improve corporate governance. The primary duties of the audit committee are to (i) review and supervise our financial reporting process and internal control system of our Group, risk management and internal audit; (ii) provide advice and comments to our Board in respect of financial, risk management and internal control matters; and (iii) perform other duties and responsibilities as may be assigned by the Board. Please see "Directors, Supervisors and Senior Management" for details about the members of our audit committee and the Board. We plan to continue strengthening our risk management policies, including anti-bribery compliances, by ensuring regular management review of relevant corporate governance measures and the implementation by each subsidiary and each corresponding department.

Data privacy

We have established procedures to protect the confidentiality of patients' personal data. We do not have access to patients' personal data. We maintain policies which require our personnel to be trained on collecting, safeguarding personal information and require our CROs to have data protection clauses in our agreements with them under which they are responsible for safeguarding data in their possession. Access to clinical trial data has

been strictly limited to authorized personnel only according to the GCP and relevant regulations. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the Informed Consent Form.

We have a number of ongoing or planned clinical studies in China and other countries. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable local data and privacy protection laws, including those in China, the United States and the EU. Together with our CROs and other collaborators, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern transfer of all clinical trial data or other potentially sensitive information. Related measures include, as applicable, ensuring that the cross-border transfer of this clinical data and information is permitted, any requisite approvals are properly obtained and applicable filings are made, in each case, with the competent authorities and in accordance with relevant laws and regulations (particularly in the case of any transfer between China and the United States). Although the laws and regulations in this area and the nature of our potential clinical studies are evolving, to date, we had not experienced any material difficulty in data transfer, and we believe our transfer of relevant clinical trial data and information between China and the United States is in the line with market practice.

For the potential impact and related risks for data privacy and security breaches, please see "Risk Factors — Risks relating to our operations — We depend on information technology and other infrastructure that are exposed to certain risks, including cyber security risks."; "Risk Factors — Risks relating to our operations — Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business"; and "Risk Factors — Risks relating to our operations — If we are found to have violated laws protecting the confidentiality of patients and other covered information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business."

ENVIRONMENTAL, WORKPLACE HEALTH AND SAFETY MATTERS

We are subject to environmental protection and occupational health and safety laws and regulations in the jurisdictions where we operate. We have instituted internal policies and systems designed to ensure our compliance with such requirements, which we believe are in line with industry standards and in compliance with the requirements of the Listing Rules.

As a biopharmaceutical company, we face a variety of environmental, health or safety-related risks associated with our operations over the short-, medium- and long-term. For example, our operations involve the use of hazardous materials, including chemicals, and may produce hazardous waste products to the environment. In addition,

we cannot eliminate the risks of contamination or personal injury from these materials. If we use hazardous materials in a manner that causes injury, we could be liable for damages as we do not maintain work injury insurance for injuries to our employees resulting from the use of hazardous materials. We also do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages. We may also incur significant costs associated with civil, administrative or criminal fines and penalties. In order to ensure that our operations are in compliance with the applicable laws and regulations, we have implemented group-wide environmental, health and safety policies and standard operating procedures, mainly comprising of management systems and procedures relating to management of process safety and hazardous substances, safety production responsibility system, employee health and safety requirements, responsibilities of the department of safety and environmental protection, etc. In particular, our environmental, health and safety protection measures include: (i) strict compliance with the GMP qualification requirements and relevant pollutant emissions standards during our production process to reduce pollutant emissions of air and wastewater. among others; (ii) implementation of safety guidelines with respect to employee health and safety, environmental protection and operational and manufacturing safety in laboratories and manufacturing facilities, and closely monitor internal compliance with these guidelines; (iii) engaging qualified third parties for the disposal of hazardous waste for all of our research and development manufacturing activities in accordance with applicable laws and regulations. In 2021 and the six months ended June 30, 2022, we transferred 15.9 tonne and 9.2 tonne hazardous waste, respectively, to the third parties; and (iv) actively implementing eco-friendly technologies and solutions and using clean energy and low-toxic and harmless raw materials where feasible. For example, we use stainless steel equipment in downstream process when producing our products, through which we can reduce the waste of single-use equipment. Furthermore, the chief executive officer is fully responsible for social, health, work safety and environmental matters. The management personnel at all levels and all employees of implement the work responsibility system step by step. We also have a dedicated group level environment, health and safety (EHS) management team responsible for overseeing our compliance with environmental, health and safety related regulations and policies, and monitoring our implementation of related internal measures, such as: (i) adopting appropriate safety measures at our facilities and implementing best practice procedures; (ii) conducting regular safety awareness training to our employees; (iii) inspecting our facilities regularly to identify and eliminate any potential safety hazards; (iv) adopting appropriate procedures regarding the disposal of any hazardous waste; (v) maintaining a system of recording and handling accidents in our facilities; and (vi) cooperating with regulatory authorities for the regular environmental compliance monitoring.

Our safety production expenses were RMB0.1 million, RMB0.5 million and RMB0.9 million in 2020, 2021 and for the six months ended June 30, 2022, respectively, the majority of which was incurred for environmental law compliance purpose. Our safety production expenses in 2021 increased because the operation and maintenance costs of environmental protection equipment and facilities and personnel costs increased according to market conditions. In addition, our production and operation scale has gradually expanded in

2021, resulting in an increase in pollutant emissions and an increase in corresponding costs. Going forward, we expect to incur a similar level of cost in relation to compliance with applicable environmental laws and regulations.

In respect of social responsibilities, it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics. We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees and communities.

We also emphasize providing a safe working environment for our employees and clinical trial participants. We incorporate work safety guidelines on safe practices, accident prevention and accident reporting as core aspects of our employee training and induction processes, and we ensure that clinical trial participants properly acknowledge their understanding of safety matters at the time of enrollment and on an ongoing basis as necessary. In addition, we have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees, including those required under the GMP standards. Furthermore, we conduct safety inspections of our laboratories and manufacturing facilities on a regular basis.

During the Track Record Period and up to the Latest Practicable Date, we were in compliance with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any workplace accident.

LICENSES, PERMITS AND APPROVALS

We are required to obtain and renew certain licenses, permits and approvals for our business operations in various jurisdictions. See "Regulatory Overview" for more information. Our Company holds a pharmaceutical manufacturing license issued by the Shandong Provincial Medical Products Administration, which is valid through August 4, 2020 to August 3, 2025. During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, permits and approvals that are material for our operations, and all of such licenses, permits and approvals were within their respective effective periods. We had not experienced any material difficulty in renewing such certificates, permits and licenses during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits and approvals.

LEGAL AND REGULATORY MATTERS

We may from time to time be involved in legal proceedings in the ordinary course of business. As of the Latest Practicable Date, there were no litigation or arbitration proceedings brought by us, or pending or threatened against us or any of our Directors, that could have a material adverse effect on our financial condition or results of operations.

During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance incident which our Directors believe would, individually or in the aggregate, have a material adverse effect on our financial condition or results of operations.

IMPACT OF COVID-19 OUTBREAK

Since December 2019, a novel strain of coronavirus or COVID-19, has become widespread in China and around the world. To contain the virus' spread, China and many other countries have taken various restrictive measures, such as lockdowns, quarantines, closure of work places, travel restrictions and home office policies.

Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 in several parts of China due to the spread of the Omicron variant, including some of our regional markets such as Shanghai, Guangdong Province, Shandong Province and Jilin Province, and various restrictive measures, such as lockdowns, quarantines, closure of work places, travel restrictions and home office policies have been implemented. As a result of the restrictive measures, our sales of Boyounuo® (BA1101) to some extent have been affected by patients' limited access to medical services in the affected regions, and we also experienced four to six months delays in the patient enrollment process of some clinical trials in China.

We set forth below the key impact of COVID-19 on major aspects of our business and operations and the measures we take to mitigate any impact.

- Clinical trials and regulatory affairs. We experienced delays in the patient enrollment process for the clinical trials of BA6101 in the EU and some clinical trials in China. Nonetheless, the COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We have not experienced and currently do not expect any material disruptions in regulatory affairs with respect to our overall development plans due to the COVID-19 pandemic. To manage the risks associated with the COVID-19 pandemic, we adopted various measures, such as cooperating with clinical trial sites to offer personal protection equipment such as masks to our enrolled patients, engaging in frequent communications with our principal investigators to identify and address any issues that may arise, suggesting the investigators to communicate with the enrolled patients on visiting local qualified hospitals for follow-up evaluations if necessary.

- Sales and marketing activities. During the COVID-19 outbreak, reduced transportations and social distancing policies have affected the organization of conferences, seminars and other offline sales and marketing activities. We have adopted flexible work-from-home practices to mitigate the impact of the COVID-19 outbreak on our sales and marketing activities.

- Daily operations and manufacturing. We followed the government's policy to prolong the Chinese Spring Festival leave. We had resumed full and normal operations since the end of February 2020. Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 in several parts of China due to the spread of the Omicron variant. To mitigate the impact on manufacturing, most of our employees remained in our Yantai Site to secure manufacturing and operations. To prevent any spread of COVID-19 in our offices and manufacturing facilities, we have implemented preventive measures such as regularly sterilizing and ventilating our offices and manufacturing facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees, and providing face masks and disinfectant to employees attending our offices and facilities. We adopted work-from-home practices during the lockdowns in Shanghai to mitigate the impact on our operations. We had resumed full and normal operations since June 2022. As of the Latest Practicable Date, we were not aware of any suspected or confirmed active COVID-19 cases on our premises.

- Supplies of raw materials and services. To some extent, reduced transportations and disruption to manufacturing and logistics networks in China due to the COVID-19 outbreak had previously affected our suppliers' abilities to manufacture and transport consumables, equipment and other supplies necessary for our operations. We have imported sufficient volume of raw materials from our overseas suppliers in advance to support our current manufacturing activities, after taking into account the potential delay in delivery. We are also actively seeking domestic suppliers for certain materials that are currently sourced from overseas suppliers. Nevertheless, as of the Latest Practicable Date, most of our suppliers had resumed normal operations and we had not experienced any material disruption or shortage of supplies since the outbreak of COVID-19.

- Financial performance. Although we generated revenue since May 2021 from the sales of Boyounuo® (BA1101), patients' limited access to medical services in the affected regions due to the COVID-19 pandemic has to some extent affected our sales performance. Furthermore, we believe we have sufficient funds on hand to support our business operation in the short to medium terms in light of the COVID-19 pandemic. For example, assuming an average cash burn rate going forward of 1.0 times of the level in 2021 of net cash used in operating related activities and taking into account the scheduled payment of our indebtedness, we estimate that our cash and cash equivalents as of October 31, 2022 will be able to maintain our financial viability for five months, or, if we also take into account the estimated [**REDACTED**] (based on the low-end of the indicative [**REDACTED**]) from the [**REDACTED**], eight months. For more details, see "Financial Information — Liquidity and capital resources — Working capital sufficiency".

However, the restrictive measures have not had any material impact on our regulatory and clinical trial plans of the Core Products and pipeline candidates, our production capability, our commercialization plans or our overall financial performance. We also believe our sales of Boyounuo® (BA1101) will resume its normal level after the lifting of various restrictive measures primarily because of its continuing strong demand in China.

The extent to which the COVID-19 outbreak impacts our business, results of operations and financial condition will depend on many factors beyond our control, including the extent of resurgences of the disease and its variants, vaccine distribution and other actions in response to the virus or to contain its impact. It is uncertain when and whether COVID-19 could be contained globally. We are closely monitoring impact of COVID-19 outbreak on us and plan to continue implementing measures necessary to ease the impact of the outbreak on our operations. While we continue to assess the impact of the COVID-19 outbreak, we are unable to accurately predict the full impact of COVID-19. We cannot assure you that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial condition or prospects. Our operations may also be adversely affected if any of our employees or employees of our distributors, suppliers and other business partners are suspected of contracting or contracted COVID-19 or become subject to restricted measures. In addition, the commencement of new clinical trials for drug candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. For more details, see "Risk Factors — Risks relating to our operations — Our business and operations could be adversely affected by the effects of health pandemics or epidemics, including the outbreak of COVID-19, in regions where we, or third parties on which we rely, have significant manufacturing facilities, concentrations of clinical trial sites or other business operations".

OVERVIEW

Immediately following the [**REDACTED**] (without taking into account any Shares which may be issued pursuant to the exercise of the [**REDACTED**]), our Controlling Shareholders, namely Luye Pharma, AsiaPharm, Luye HK, Yantai Luye and Shandong Luye, will be interested in an aggregate of approximately [**REDACTED**]% of our Company's total share capital.

As of the Latest Practicable Date, Shandong Luye was wholly owned by Yantai Luye, which in turn is indirectly wholly owned by Luye Pharma through AsiaPharm and Luye HK. Accordingly, Luye Pharma, AsiaPharm, Luye HK, Yantai Luye and Shandong Luye constitute a group of our Controlling Shareholders under the Listing Rules.

Luye Pharma is a company listed on the Main Board of the Stock Exchange (stock code: 2186), which principally engages in the research, development, manufacturing, marketing, and sale of chemical drugs through its subsidiaries. Each of AsiaPharm and Yantai Luye is an investment holding company. Luye HK principally engages in the distribution and sale of pharmaceutical products and investment holdings. Shandong Luye principally engages in the manufacture and sale of pharmaceutical products.

DELINEATION OF BUSINESS

There is clear delineation between our business and the businesses of the Luye Group. We mainly engage in developing, manufacturing and commercializing biologics, while the Luye Group mainly engages in the research, development, manufacturing, marketing, and sale of chemical drugs.

Significant differences between biologics and chemical drugs

The table below sets forth the significant distinctions between biologics (macro-molecular), i.e. the business focus of our Group, and the non-biological (mainly micro-molecular) chemical drugs, i.e. the business focus of the Luye Group:

Distinctions	Biologics	Chemical drugs
Different mechanisms of action	• Biologically derived from living organisms or cells. • High specificity — biologics identify antigen on the surface of tumor cells and various receptors, precisely targeting at the cancer cells and reacting distinctively with targets. • Biologics can inhibit growth of cells after cells cycles and promote cell apoptosis, so as to kill the cancer cells through a combination of mechanisms involving action between antibody-dependent cell-mediated cytotoxicity (ADCC), complement dependent cytotoxicity (CDC), and antibodies and molecules.	• Chemically derived • Used to treat a variety of diseases and conditions and can be quite diverse in their mechanisms of action. • Because of their small size and typical physicochemical properties, small molecules can be effective enzyme inhibitors and allosteric modifiers and can target extracellular proteins or intracellular receptors in the cytosol, nuclei, and central nervous system.
Differences in development and production technology	• Biologics consist of complicated molecular structures and have high molecular weights. For biologics, structural characterisation is more complicated than small molecules, but it is a essential part of the development and quality control process. Various antibody-based assays have been been used to address the challenge of quantification of biologics. • Biologics involve complicated molecular biology and genetic engineering technology, which include antibody engineering technology, cell culture medium and technology for developing hybridoma producing macromolecular biologics. Production of chemical drugs does not involve such technologies.	• Chemical drugs generally have well-defined chemical structures, and a finished drug can usually be analyzed to determine all its various components through traditional laboratory methods. • Development and production of chemical drugs mainly involve technologies for deriving such drugs from chemicals including the technologies for producing (i) freeze-dried chemical powder; (ii) drug tablets, capsules and granules; and (iii) medical patches. Chemical drugs generally take less than a week to manufacture.

Distinctions	Biologics	Chemical drugs
	• Given that biologics are sensitive to and vulnerable to changes in the pH, temperature, and osmotic pressure of the environment, the R&D and manufacturing of biologics involve complicated biopharmaceutical technology, high level of requirements in respect of production specifications, as well as time and labor-consuming process. Biologics, being more complicated in nature, may take more than one month to manufacture. In light of the above, the production of biologics require manufacturing facilities separate and distinct from those for chemical drugs	
Differences in treatment application and usage	• Biologics are highly specific, and would generally target patients with medical conditions which are suitable for treatment targeting a specific biomarker expressed on body cells. In particular, biologics are used for reinforcing the anti-cancer efficacy of chemical drugs in treatment known as combination therapies. In terms of targeted patients, unlike chemical drugs, which are generally used across all stages of cancer (e.g. early stage, before and/or after surgery, and late stage), biologics are used on a cancer type-specific, or even on a patient specific basis.	• As the mechanism of actions of chemical drugs are diverse, chemical drugs of the Luye Group would target patients with medical conditions which are suitable for a treatment generally on body cells or a certain type of body cells.

Largely different medical indications

The majority of the existing products or key pipeline products of our Group and the Luye Group have no overlap in medical indications. Accordingly, the products of our Group and the Luye Group mostly target patients with different medical conditions. The summary below compares the principal types of existing products between our Group and the Luye Group and their respective overlapping indications:

Our Group	The Luye Group	Drugs with overlapping indications
• Antitumor drugs	• Antitumor drugs	Among these antitumor drugs, only Boyounuo® (BA1101) of our Company has overlapping indications with Lipusu of the Luye Group (and potentially LY01616 of the Luye Group which is still under its Phase 1 clinical trial and thus the specific tumor which it targets has not been fixed), but they are applied in different combination treatment methods and differ in multiple aspects including their uses in first-line, second-line or third-line treatments.
• Osteoporosis drugs	• Osteoporosis drugs	Among these osteoporosis drugs, only BA6101 of our Company and Sidinuo of the Luye Group have overlapping indications in relation to the treatment of osteoporosis. However, there is no material or potential competition as BA6101 primarily targets postmenopausal women with osteoporosis at high risk for fracture, whereas Sidinuo targets patients with osteoporosis in general and related bone pain.

Our Group	The Luye Group	Drugs with overlapping indications
• Virology drugs	• Cardiovascular drugs	Not applicable.
• Eye disease drugs	• Alimentary tract & metabolism drugs	
	• Central nervous system drugs	
	• Other drugs, including Keweijia, Fengshiye, Tongke and other drugs in the pipeline including drug candidates for hyperlipidemia and contraception, respectively	

The aforementioned products with overlapping indications are not sold by our Group or the Luye Group on a bundled basis. It is not necessary for our products to be used together with the products of the Luye Group. In particular, the products set out above can be administered independently from each other, depending on the requirements of the particular treatment. In certain cases, our products may be used in combination with products of the Luye Group but they are not replaceable or in competition with each other. The targeted patient groups or the recommended lines of therapy for treating the diseases of the aforementioned products with overlapping indications differ from each other.

Having considered the factors set out above, our Directors believe and the Joint Sponsors concur that there is clear delineation between our business and the businesses of the Luye Group. Based on the above, our Directors are of the view that there is no direct or indirect competition between the biologics of our Group and chemical drugs of the Luye Group and thus the Retained Business does not compete and is unlikely to compete, directly or indirectly, with our Group's business.

As of the Latest Practicable Date, none of our Controlling Shareholders had any interest in any business which competes or is likely to compete, either directly or indirectly with our Company's business which would require disclosure under Rule 8.10 of the Listing Rules.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

We believe that we are capable of carrying on our business independently of our Controlling Shareholders and their respective close associates (other than our Group) after the [**REDACTED**] for the following reasons:

Management independence

Our Board comprises two executive Directors, four non-executive Directors, and three independent non-executive Directors. From September 2005 to September 2020, Ms. Jiang Hua, our chief executive officer, chairlady of our Board and one of our executive Directors, served as a vice president in the Luye Group, where she was primarily responsible for the Luye Group's investment, strategy and business development and investor relations management. Other than three of our non-executive Directors, namely Dr. Li Youxin, Mr. Liu Yuanchong and Ms. Li Li, none of our Directors or the members of our senior management team holds any position in the Luye Group. Given that Dr. Li Youxin, Mr. Liu Yuanchong and Ms. Li Li are all members of Luye Pharma's senior management and our non-executive Directors, they will not be involved in the day-to-day management and operations of our business and will contribute from a non-executive capacity at the Board-level. Save as disclosed above, none of the senior management of our Company or key members of our R&D department had any roles and responsibilities in the Luye Group during the Track Record Period and up to the Latest Practicable Date.

Each of our Directors is aware of his/her fiduciary duties as a director of our Company which require, among other things, that he/she acts for the benefit and in the best interests of our Company and does not allow any conflict between his/her duties as a Director and his personal interest. In the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and our Directors or their respective associates, the interested Director(s) shall abstain from voting at the relevant Board meetings of our Company in respect of such transactions and shall not be counted towards the quorum. In addition, we have an independent senior management team to carry out the business decisions of our Group independently.

Having considered the above factors, our Directors are satisfied that they are able to perform their roles in our Company independently, and our Directors are of the view that we are capable of managing our business independently from our Controlling Shareholders and their respective close associates following the completion of the [**REDACTED**].

Operational independence

Although our Controlling Shareholders will retain a controlling interest in our Company after [**REDACTED**], we have full rights to make all decisions on, and to carry out, our own business operations independently from our Controlling Shareholders and their respective close associates and will continue to do so after the [**REDACTED**]. Our Group is able to operate without reliance on our Controlling Shareholders and their respective close associates.

Research and development (R&D)

We conduct our R&D independently of the Luye Group. All of our Core Products and Commercialized Product were developed by our own R&D departments and personnel, despite a limited number of staff members of the Luye Group who were involved in the provision of certain organization, coordination or other support services for clinical trials of some of these products. The key R&D members responsible for the development of our Core Products and Commercialized Product include Dr. Dou Changlin (our executive Director, president of R&D and chief operating officer), Mr. Lu Jun (our senior vice president and head of biotechnology engineering center and quality department), Mr. Song Deyong (in charge of biopharmaceutical discovery research team), Mr. Shen Zhenduo (in charge of biopharmaceutical analysis research team) and Mr. Sun Baiping (in charge of biological activity research team), all of whom have remained with us since we commenced the development of such products. See "Directors, Supervisors and Senior Management" for further details of Dr. Dou Changlin, Mr. Lu Jun and Mr. Song Deyong. Mr. Shen Zhenduo and Mr. Sun Baiping has more than 13 years and 11 years of experience in the biopharmaceutical industry, respectively, and they both joined our Company in March 2014 and served in successive roles in our biopharmaceutical analysis research team and biological activity research team, respectively. We have set up a range of departments and teams to focus on R&D related work. During the Track Record Period and up to the Latest Practicable Date, all of our key technology talents and R&D staff have entered into employment contracts with our Group. We have our own equipment and facilities required for R&D and the production lines dedicated to the development and production of antibody drugs. The R&D systems, capabilities, and technologies of our Company are completely independent from those of the Luye Group due to the different product types.

Intellectual property rights and licenses required for operation

As of the Latest Practicable Date, our Group was the registered owner of 24 invention patents in China, and had a number of pending patent applications. Such intellectual property rights cover our major product candidates. Save for the trademark licensing agreement disclosed below, our Group will not rely on the Luye Group for licensing of intellectual property rights after its separate [**REDACTED**].

Shandong Luye entered into a trademark licensing agreement with our Company in relation to the licensing of a trademark by the Luye Group to our Group. See "Connected Transactions" in this document for further details in relation to the relevant trademark licensing agreement. Our Directors consider that the trademark licensing agreement was entered into on normal commercial terms and thus does not affect or impair our operational independence. Save for such trademark licensing agreement, we are not licensed with any trademarks from the Luye Group, and we hold and enjoy the benefit of all relevant licenses and qualifications necessary to carry on our current business operations.

Production and business premises

We have our own production and business premises, as well as production systems, auxiliary production systems, and supporting facilities for our business operation, which are separate from those of the Luye Group. We either own or lease our major factories, machinery, and equipment, and we have the ownership or right of use to the trademarks and patents related to our production and operation.

Although our Group leased certain office premise, warehouse and R&D related facilities from the Luye Group as of the Latest Practicable Date, similar facilities or office space can be readily identified on the market. Other than the leases, we have engaged, and expect to continue to engage after the [**REDACTED**], the Luye Group for testing services and environmental, health and safety management services. For the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, the aggregate expenses incurred by our Group for such services from the Luye Group accounted for approximately 0.32%, 0.25% and 0.17% of our total costs and expenses for the respective years. Further, the provision of certain testing services from the Luye Group is expected to cease in or around August 2022. See "Connection Transactions" for further details. Our Company believes the above transactions between our Group and the Luye Group are not material to our Group in terms of their nature and transaction amounts and do not affect our operational independence from the Luye Group.

Procurement

We are able to procure raw materials independently and to negotiate and enter into procurement contracts with raw material suppliers separate from the Luye Group. We have an independent procurement department in charge of the raw material procurement and supplier management.

Whilst there are certain overlaps between the suppliers of our Group and the Luye Group, our Directors are of the view that procurement from overlapping suppliers does not result in any reliance on the Luye Group:

(a) our Group has established its own supplier selection and management system, and has formulated its own suppliers list. All the provisions and terms of the procurement agreements are directly negotiated between our Group and the relevant counterparties. During the procurement process, we conduct screening of supplier candidates to ensure that such suppliers can provide high-quality products at competitive prices. We take the initiative to collect supplier information and to identify suppliers that match our commercial needs. The existence of overlapping suppliers is the result of market-oriented selections, and all decisions are made by our Group based on our independent judgment;

(b) our Group is able to enter into business relationships with these suppliers independently from the Luye Group in the ordinary course of business and also enter into service agreements with the relevant suppliers without any involvement of the Luye Group. While such suppliers may not be readily replaceable given the limited number of comparable suppliers, our Company believes that its relationships with these vendors are independently maintained and clearly delineated from that of the Luye Group; and

(c) for the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, the majority of the purchases of our Group from these overlapping suppliers were mainly related to purchases of materials, construction costs, equipment purchases as well as logistics and marketing services. Our Group is able to separately enter into procurement or service agreements with these suppliers and the relevant vendors independent of the Luye Group. There exists a good variety of similar vendors providing the same services and products at comparable pricing in the industry and any changes in vendors for such supplies are not expected to result in any material impact on our business and operations. For the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, the remaining purchases were mainly related to clinical trial services from medical institutions and testing institutions. While such suppliers may not be readily replaceable given the limited number of comparable suppliers in the market, we would assess and compare terms of services offered by these comparable suppliers in the market for the services we require and select the suitable suppliers based on factors such as the pricing, quality of services and track record and reputation of the suppliers. We have maintained a stable relationship with such suppliers and we believe that such relationships are independently maintained and clearly delineated from that of the Luye Group.

Sales and marketing

We have established a commercial operation center responsible for sales and marketing. We have our own sales team and maintain our own distribution network and negotiate with our distributors independently and separately from the Luye Group. Our products are not sold to the distributors together with the Luye Group on a bundled basis. Our Group and the Luye Group do not share promotion and distribution costs, sales channels, or sales resources. Further, we have independently entered into promotion agreements with independent third parties for the commercialization of our products during the Track Record Period.

We generated no revenue for the year ended December 31, 2020. For the year ended December 31, 2021, we recorded a total revenue of approximately RMB158.7 million, which were generated from the sale of Boyounuo® (BA1101), and a large proportion of such revenue was attributable to sales to overlapping distributors between our Group and the Luye Group. The existence of such overlapping distributors was primarily due to the limited number of distributors with the necessary qualifications for pharmaceutical distribution in the PRC. Nonetheless, we evaluate our distributors on an individual basis, negotiate the contractual arrangements with each of these distributors independently, and enter into independent contractual agreements, thereby maintaining our operational independence from the Luye Group.

Independence of administrative management

We have established the necessary administrative departments responsible for our business operations, which are independent from the Luye Group. We do not rely on the Luye Group and we have independent production, R&D, sales and procurement systems for our principal business. As detailed in the section headed "Connected Transactions" in this document, our Group and the Luye Group share certain non-essential administrative services on a cost basis. Notwithstanding any sharing of resources to optimize the administration costs structure of our Group, all essential functions involving any management decision or discretion will be retained and performed by our Group independently of the Luye Group. We have established an independent functional organization system. All employees have signed their employment contracts with our Group exclusively.

Save for the continuing connected transactions between the Luye Group and our Group disclosed in the section headed "Connected Transactions", our Directors do not expect that there will be any other continuing connected transaction between the Luye Group and our Group immediately after **[REDACTED]**.

Based on the above, our Directors are of the view that our Group has been operating independently from our Controlling Shareholders and their respective close associates during the Track Record Period and will continue to operate independently.

Financial independence

We have established our own finance department with a team of financial staff which is responsible for financial control, accounting, reporting, group credit and internal control of our Group, which is independent from the Luye Group.

As of June 30, 2022, the Luye Group has provided guarantees for loans we borrowed, of which the outstanding principal amount was approximately RMB245 million in aggregate. All the aforesaid guarantees will be fully released on or before [**REDACTED**].

All of our amounts due to the Luye Group which were non-trade in nature will be settled in full on or before [**REDACTED**].

Accordingly, our Directors are of the view that our Group is capable of maintaining financial independence from the Luye Group.

CORPORATE GOVERNANCE MEASURES

As illustrated above and in "Business" in detail, biologics are the focus of our Group's business whereas the Luye Group focuses on chemical drugs. To ensure continued business delineation between our Group and the Luye Group and to manage any potential conflicts of interest, our Company and Luye Pharma [have] adopted the following corporate governance measures:

(a) in the event that any new investment or other business opportunity which predominantly relates to the research, development, manufacturing, marketing and sale of biologics (the "**Biologics Business**") is identified or is made available to the Luye Group, Luye Pharma shall refer such opportunity to our Company on a timely basis by giving written notice to our Company within 30 business days of identifying such opportunity, the nature of such opportunity, the investment or acquisition costs and all other details reasonably necessary for our Company to consider whether to pursue such opportunity, followed by the procedures below:

    (i) upon receiving the notice, our Company shall seek approvals from all of our independent non-executive Directors who do not have an interest in the opportunity (the "**Boan INEDs**") as to whether to pursue or decline the opportunity (any director who has actual or potential interest in the opportunity shall abstain from attending and voting at, and shall not be counted in the quorum for, any meeting convened to consider such opportunity);

    (ii) the Boan INEDs shall, within 30 days of receipt of the offer notice, inform Luye Pharma in writing on behalf of our Company its decision whether to pursue or decline the opportunity; and

    (iii) the Luye Group shall be entitled, but not obliged, to pursue such opportunity if Luye Pharma receives a notice from the Boan INEDs declining such opportunity, or if the Boan INEDs fails to respond within the 30-day period as mentioned above;

(b) in the event that any new investment or other business opportunity which does not predominantly relate to the Biologics Business is identified or is made available to our Group, our Company shall refer such opportunity to Luye Pharma on a timely basis by giving written notice to Luye Pharma within 30 business days of identifying such opportunity, the nature of such opportunity, the investment or acquisition costs and all other details reasonably necessary for Luye Pharma to consider whether to pursue such opportunity, followed by the procedures below:

(i) upon receiving the notice, Luye Pharma shall seek approvals from all the independent non-executive directors of Luye Pharma who do not have an interest in the opportunity (the "**Luye INEDs**") as to whether to pursue or decline the opportunity (any director who has actual or potential interest in the opportunity shall abstain from attending and voting at, and shall not be counted in the quorum for, any meeting convened to consider such opportunity);

(ii) the Luye INEDs shall, within 30 days of receipt of the offer notice, inform our Company in writing on behalf of Luye Pharma its decision whether to pursue or decline the opportunity; and

(iii) our Group shall be entitled, but not obliged, to pursue such opportunity if our Company receives a notice from the Luye INEDs declining such opportunity, or if the Luye INEDs fails to respond within the 30-day period as mentioned above;

(c) in the event that the an investment or business opportunity which cannot be determined as predominantly related to the Biologics Business or not is identified or is made available to our Group or the Luye Group, such opportunity shall be referred to the respective boards of directors of our Company and Luye Pharma, which shall enter into discussions in good faith to agree on whether and how to approach such opportunity on a fair and equitable basis;

(d) our Group and the Luye Group shall enter into separate procurement contracts with suppliers independently and shall have separate procurement teams with no overlapping personnel for raw material procurement and supplier management;

(e) our Group and the Luye Group shall enter into separate business contracts with customers independently and shall have separate sales and marketing teams with no overlapping personnel;

(f) as part of our preparation for the [**REDACTED**], we have amended our Articles of Association to comply with the Listing Rules. In particular, our Articles of Association provides that, unless otherwise provided, a Director shall not vote on any resolution approving any contract or arrangement or any other proposal in which such Director or any of his/her close associates have a material interest nor shall such Director be counted in the quorum present at the meeting;

(g) we are committed that our Board should include a balanced composition of executive and non-executive Directors (including independent non-executive Directors). We have appointed three independent non-executive Directors and we believe our independent non-executive Directors possess sufficient experience and they are free of any business or other relationship which could interfere in any material manner with the exercise of their independent judgment and will be able to provide an impartial and external opinion to protect the interests of our public Shareholders. Details of our independent non-executive Directors are set out in the section headed "Directors, Supervisors and Senior Management" in this document. The independent non-executive Directors of our Company shall give their independent opinions to the Shareholders on the relevant connected transaction(s) pursuant to the Listing Rules;

(h) the day-to-day operation of our Group is overseen by our executive Directors and our senior management which do not hold any position in the Luye Group, and there is no overlap of directors or senior management between our Group and the Luye Group except for three of our non-executive Directors, namely Dr. Li Youxin, Mr. Liu Yuanchong and Ms. Li Li as disclosed above;

(i) in the event that the independent non-executive Directors are requested to review any conflicts of interests between our Company on the one hand and Luye Pharma on the other hand, Luye Pharma and/or our Directors shall provide the independent non-executive Directors with all necessary information and our Company shall disclose the decisions of the independent non-executive Directors either through our annual report or by way of announcements;

(j) our Directors shall abstain from voting on any Board resolutions approving any contract or arrangement or any other proposal with Luye Pharma in which they have a material interest. In such a situation, our Directors who do not have any ongoing role with Luye Pharma will vote and decide on such matters. In this context, a conflict, so far as our Company is concerned, will be taken to include any matter in which Luye Pharma has a direct or indirect interest;

(k) our Directors (including the independent non-executive Directors) will seek independent and professional opinions from external advisers at our Company's cost as and when appropriate in accordance with the Code on Corporate Governance Practices and Corporate Governance Report as set out in Appendix 14 to the Listing Rules;

(l) any transactions between our Company and its connected persons shall be in compliance with the relevant requirements of Chapter 14A of the Listing Rules, including the announcement, annual reporting and independent shareholders' approval requirements (if applicable) under the Listing Rules; and

(m) our Company has appointed Maxa Capital Limited as our compliance adviser and will appoint a Hong Kong legal adviser upon completion of the [**REDACTED**], which will provide advice and guidance to us in respect of compliance with the Listing Rules and applicable laws, rules, codes and guidelines, including but not limited to various requirements relating to Directors' duties and internal controls. Therefore, our Directors believe that our Company has sufficient and effective control mechanisms to ensure that our Directors perform their respective duties properly and safeguard the interests of our Company and our Shareholders as a whole.

OVERVIEW

One-off transactions with the Luye Group

Prior to the [**REDACTED**], our Group has entered into a number of property leasing agreements with members of the Luye Group, pursuant to which (i) our Group leased one office premise in the PRC with a total GFA of approximately 4,900 sq.m. from the Luye Group at the annual rent of approximately RMB1.8 million; and (ii) our Group leased four properties in the PRC with an aggregate GFA of approximately 1,608 sq.m. from the Luye Group, comprising a cell and genetic therapy R&D facility, analytical equipment room, storage unit and testing laboratory, at the aggregate annual rent of approximately RMB0.8 million. Instead of incurring material capital expenditures for constructing our own premises, we leased such premises so that we could allocate a substantial part of our cashflow to R&D activities.

Considering that any relocation of facility or change of the current lease arrangements may cause disruption to our business operations and incur additional relocation costs, our Directors are of the view that it is in the interest of the Group to continue to lease such premises from the Luye Group. In accordance with IFRS 16 "Leases", the aforementioned leases are recognized as right-of-use assets on our consolidated statements of finance position. Accordingly, the entering into of such leases are regarded as one-off acquisitions of assets, rather than continuing transactions. While the lessors in such leases will, upon [**REDACTED**], become our Company's connected persons (as defined under Chapter 14A of the Listing Rules), the transactions under such leases (being one-off transactions entered into prior to [**REDACTED**]) will not be classified as connected transactions or continuing connected transactions of our Company under Chapter 14A of the Listing Rules.

Continuing connected transactions

Our Group has entered into a number of continuing transactions in our ordinary and usual course of business with Shandong Luye and Yantai Luye, which, each being one of our Controlling Shareholders, will become connected persons of our Company upon [**REDACTED**]. Upon [**REDACTED**], such transactions will constitute continuing connected transactions under Chapter 14A of the Listing Rules, details of which are set out below.

CONTINUING CONNECTED TRANSACTIONS FULLY EXEMPTED FROM THE REPORTING, ANNUAL REVIEW, ANNOUNCEMENT, CIRCULAR AND INDEPENDENT SHAREHOLDERS' APPROVAL REQUIREMENTS

1. Trademark Licensing

On April 1, 2022, our Company entered into a trademark licensing agreement (the "**Trademark Licensing Agreement**") with Shandong Luye, pursuant to which Shandong Luye agreed to grant to our Company and our subsidiaries from time to time the right to use the trademark "" (the "**Licensed Trademark**") registered in Hong Kong (Registration number: 304792816) for a term commencing from April 1, 2022 to December 31, 2024 on a royalty-free basis. See "Statutory and General Information — B. Further information about our business — 2. Intellectual property rights of our Group" in Appendix VI to this document for details of the Licensed Trademark.

Reasons for the transaction

We consider the "Luye" brand reflects our corporate identity and represents the quality of our products.

Implications under the Listing Rules

Shandong Luye is one of our Controlling Shareholders and thus a connected person of our Company upon [**REDACTED**]. Accordingly, the transactions under the Trademark Licensing Agreement will constitute continuing connected transactions for our Company under Chapter 14A of the Listing Rules upon [**REDACTED**].

As the right to use the Licensed Trademark is granted to our Company and our subsidiaries on a royalty-free basis, the transactions under the Trademark Licensing Agreement will fall below the de minimis threshold provided under Rule 14A.76 of the Listing Rules upon [**REDACTED**] and will be exempt from the reporting, annual review, announcement, circular and independent Shareholders' approval requirements under Chapter 14A of the Listing Rules.

2. Sharing of Administrative Services

On February 28, 2022, our Company and Yantai Luye entered into a share of administrative services agreement (as supplemented by a supplemental agreement thereto dated May 5, 2022 entered into among our Company, Yantai Luye and Shandong Luye, the "**Share of Administrative Services Agreement**") pursuant to which our Company agreed to share the fees charged on the Luye Group by Independent Third Parties for the provision of certain office administrative information system support services to our Group and the Luye Group (collectively, the "**Administrative Services**"). The Share of Administrative Services Agreement has a term commencing from the date of such agreement to September 30, 2024. The annual service fees for the Administrative Services were determined on a cost basis, and our Company's share of such annual service fees was determined based on the ratio of the approximate number of users of such services or the number of software units used, as the case may be, in our Group to that of the Luye Group.

Reasons for the transaction

We had been using such non-essential Administrative Services together with the Luye Group. We believe such arrangement with the Luye Group can optimize the administration costs structure of our Group.

Historical transaction amounts

For the two years ended December 31, 2021 and the six months ended June 30, 2022, the historical transaction amounts in respect of the service fees paid by us to Yantai Luye and Shandong Luye for the Administrative Services amounted to nil, nil and RMB62,000, respectively. There was no historical transaction amount for sharing the services fees for the Administrative Services for the two years ended December 31, 2021 as the Luye Group did not require us to share such costs given that the amount of annual service fees for the Administrative Services were immaterial during the two years ended December 31, 2021.

Annual caps

Our Directors estimate that the maximum amounts of service fees shared by our Company for the Administrative Services contemplated under the Share of Administrative Services Agreement for the years ending December 31, 2022, 2023 and 2024 will not exceed RMB227,448, RMB134,862 and RMB21,209, respectively.

Implication under the Listing Rules

Each of Shandong Luye and Yantai Luye is one of our Controlling Shareholders and thus a connected person of our Company upon [**REDACTED**]. Accordingly, the transactions under the Share of Administrative Services Agreement will constitute continuing connected transactions for our Company under Chapter 14A of the Listing Rules upon [**REDACTED**]. As the Administrative Services shared between our Company and the Luye Group are on a cost basis, identifiable and are allocated to our Company and the Luye Group on a fair and equitable basis, the transactions under the Share of Administrative Services Agreement will fall under the share of administrative services exemption provided under Rule 14A.98 of the Listing Rules upon [**REDACTED**], and thus the transactions thereunder will be exempt from the reporting, annual review, announcement, circular and independent Shareholders' approval requirements under Chapter 14A of the Listing Rules.

3. Testing services

On March 28, 2022, our Company entered into a service agreement (the "**Testing Service Agreement**") with Shandong Luye, pursuant to which Shandong Luye agreed to provide testing services, including but not limited to specific materials identification, microbial identification, seal integrity testing and animal testing (collectively, the "**Testing Services**"), to our Group. The Testing Service Agreement has a term commencing from the date of such agreement to December 31, 2023, which may be renewed as the parties may mutually agree, subject to the compliance with the requirements under Chapter 14A of the Listing Rules and all other applicable laws and regulations. Service fees for the Testing Services are charged at a fixed unit rate based on the type and amount of services provided. The service fees for the Testing Services are determined with reference to the actual cost (including the costs of testing materials) incurred by Shandong Luye. To ascertain the prevailing market rate for similar services, we would obtain quotations for such services from independent suppliers in the market.

Reasons for the transaction

As a biotechnology company, we require Testing Services for the materials used in our operations and for other purposes in our R&D activities. We started to engage Shandong Luye for such services in July 2020 as we did not have our own testing laboratory and our quality control department lacked the capability to carry out our own Testing Services. We consider that Shandong Luye has been providing testing services of good quality at a reasonable fee rate during the Track Record Period and due to the long-term and stable cooperation relationship between Shandong Luye and our Group, we believe Shandong Luye will continue to provide such services to us in a timely and cost-efficient manner.

Historical transaction amounts

For the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, the historical transaction amounts in respect of the service fees paid by us to Shandong Luye for the Testing Services amounted to approximately RMB697,000, RMB663,000 and RMB39,000, respectively.

Annual caps

Our Directors estimate that the maximum amounts of service fees payable by our Company to Shandong Luye for the Testing Services contemplated under the Testing Service Agreement for the years ending December 31, 2022 and 2023 will not exceed RMB103,393, and RMB20,955, respectively.

Our Directors have primarily considered the relevant historical transaction amounts, expected R&D activities and amount of related Testing Services required in arriving at the above annual caps which are considered to be reasonable and justifiable in the circumstances.

The decrease in the relevant proposed annual caps as compared to our historical transaction amounts during the Track Record Period is primarily due to the expected cessation of certain Testing Services to be provided by Shandong Luye to us since we expect to purchase and start to utilize equipment for the relevant testing processes in or around August 2022. Despite that, we will continue to engage Shandong Luye to provide certain animal testing services and specific materials identification services to a limited extent as our in-house quality control laboratory does not have such functions. As a result of the above, we also expect a further drop in the proposed annual cap for the year ending December 31, 2023, as compared to that for the year ending December 31, 2022.

Implication under the Listing Rules

Shandong Luye is one of our Controlling Shareholders and thus a connected person of our Company upon [**REDACTED**]. Accordingly, the transactions under the Testing Service Agreement will constitute continuing connected transactions for our Company under Chapter 14A of the Listing Rules upon [**REDACTED**].

Since each of the applicable percentage ratios under the Listing Rules in respect of the annual caps for the Testing Service Agreement is expected to be less than 5% and the total consideration thereunder is expected to be less than HK$3,000,000 on an annual basis, the transactions under the Testing Service Agreement will be exempt from the reporting, annual review, announcement and independent shareholders' approval requirements.

4. EHS services

On March 28, 2022, our Company entered into an environmental, health and safety management ("**EHS**") service agreement (the "**EHS Service Agreement**") with Shandong Luye, pursuant to which Shandong Luye agreed to provide EHS services, including wastewater treatment and provision of sites for temporary hazardous waste storage, for our operations (the "**EHS Services**") to our Group. The EHS Service Agreement has a term commencing from the date of such agreement to December 31, 2023, which may be renewed as the parties may mutually agree, subject to the compliance with the requirements under Chapter 14A of the Listing Rules and all other applicable laws and regulations. Service fees for EHS Services are charged at a fixed unit rate based on the volume of the wastewater processed as measured in tons and a fixed monthly rate for the usage of the waste storage sites. The service fees for EHS Services are determined with reference to the (i) facilities maintenance fees; and (ii) actual cost (including labor cost) incurred by Shandong Luye. To ascertain the prevailing market rate for similar services, we would obtain quotations for such services from independent suppliers in the market.

Reasons for the transaction

We had engaged Shandong Luye to provide EHS Services since (i) our Company does not have our own in-house facilities for wastewater treatment; and (ii) Shandong Luye operates a central wastewater treatment facility which is geographically and logistically more convenient for our Group to dispose and treat our wastewater on-site as compared to engaging an external Independent Third Party to do so. We believe that it will be cost efficient to continue engaging Shandong Luye for such services whilst we focus our resources on our R&D activities.

Historical transaction amounts

For the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, the historical transaction amounts in respect of the service fees paid by us to Shandong Luye for the EHS Services amounted to approximately RMB119,000, RMB331,000 and RMB611,000, respectively.

Annual caps

Our Directors estimate that the maximum amounts of service fees payable by our Company to Shandong Luye for the EHS Services contemplated under the EHS Service Agreement for the years ending December 31, 2022 and 2023 will not exceed RMB1,261,700 and RMB1,541,364, respectively.

Our Directors have primarily considered the relevant historical transaction amounts, the amount and type of clinical trials and other R&D and production activities to be carried out in the two years ending December 31, 2023 in arriving at the above annual caps which are considered to be reasonable and justifiable in the circumstances.

The increase in the relevant proposed annual caps as compared to our historical transaction amounts during the Track Record Period is primarily due to the expected increase in (i) clinical trials and development of our pipeline products; (ii) our R&D planned to be carried out for the two years ending December 31, 2023; and (iii) facilities maintenance fees and labor costs.

Implication under the Listing Rules

Shandong Luye is one of our Controlling Shareholders and thus a connected person of our Company upon [**REDACTED**]. Accordingly, the transactions under the EHS Service Agreement will constitute continuing connected transactions for our Company under Chapter 14A of the Listing Rules upon [**REDACTED**].

Since each of the applicable percentage ratios under the Listing Rules in respect of the annual caps for the EHS Service Agreement is expected to be less than 5% and the total consideration thereunder is expected to be less than HK$3,000,000 on an annual basis, the transactions under the EHS Service Agreement will be exempt from the reporting, annual review, announcement and independent shareholders' approval requirements.

5. Yantai Property lease

On July 18, 2022, our Company entered into a property lease agreement (the "**Yantai Property Lease Agreement**") with Shandong Luye, pursuant to which Shandong Luye agreed to lease one property in Yantai, Shandong Province of the PRC with a total GFA of 1,173 sq.m. (the "**Yantai Property**") to our Group for warehouse purposes. The Yantai Property Lease Agreement has a term commencing from August 1, 2022 to July 31, 2023, which may be renewed as the parties may mutually agree, subject to the compliance with the requirements under Chapter 14A of the Listing Rules and all other applicable laws and regulations. The rentals to be paid under the Yantai Property Lease Agreement was determined on an arm's length basis with reference to the historical rental amounts during the Track Record Period and the prevailing market rent of similar properties located in similar areas and should be not less favourable than that offered by Independent Third Parties.

Reasons for the transaction

We had been leasing the Yantai Property from Shandong Luye since August 2021. To minimize disruptions to our business and considering that the rentals of the Yantai Property are in line with the prevailing market rent for comparable properties in the area, our Group will continue to lease the Yantai Property from Shandong Luye after [**REDACTED**].

Historical transaction amounts

For the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022, the historical transaction amounts in respect of the rentals paid by us to Shandong Luye for the Yantai Property amounted to nil, approximately RMB164,000 and RMB196,000, respectively.

Annual caps

Our Directors estimate that the maximum amounts of rentals payable by our Company to Shandong Luye for the lease of the Yantai Property contemplated under the Yantai Property Lease Agreement for the years ending December 31, 2022 and 2023 will not exceed RMB428,145 and RMB249,751, respectively, based on the fixed rentals of the Yantai Property as set out in the Yantai Property Lease Agreement.

Implication under the Listing Rules

Shandong Luye is one of our Controlling Shareholders and thus a connected person of our Company upon [**REDACTED**]. Accordingly, the transactions under the Yantai Property Lease Agreement will constitute continuing connected transactions for our Company under Chapter 14A of the Listing Rules upon [**REDACTED**].

Since each of the applicable percentage ratios under the Listing Rules in respect of the annual caps for the Yantai Property Lease Agreement is expected to be less than 5% and the total consideration thereunder is expected to be less than HK$3,000,000 on an annual basis, the transactions under the Yantai Property Lease Agreement will be exempt from the reporting, annual review, announcement and independent shareholders' approval requirements.

BOARD OF DIRECTORS

Our Board of Directors comprises of nine Directors, including two executive Directors, four non-executive Directors and three independent non-executive Directors. The powers and duties of our Board include determining our business and investment plans, preparing our annual financial budgets and final reports, and exercising other powers, functions and duties as conferred by the Articles. We have entered into service agreements with our executive Directors and a letter of appointment with each of our non-executive Directors and independent non-executive Directors.

The table below sets out certain information in respect of our Directors:

Name	Age	Existing position(s) in our Group	Date of joining our Group	Date of appointment as Director	Roles and responsibilities
Executive Directors					
Ms. Jiang Hua (姜華)	[44]	Executive Director, chief executive officer and chairlady of our Board	June 22, 2020	June 22, 2020	Overseeing the corporate management, strategic and business development of our Group and overseeing our Board
Dr. Dou Changlin (竇昌林)	[59]	Executive Director, president of R&D and chief operating officer	December 31, 2013	November 16, 2019	Formulating the R&D and product line development strategies, implementing the R&D activities and overseeing the management of drug development processes of our Group
Non-executive Directors					
Dr. Li Youxin (李又欣)	[60]	Non-executive Director and vice chairman of our Board	June 22, 2020	June 22, 2020	Providing strategic advice and recommendations on the operations and management of our Group

Name	Age	Existing position(s) in our Group	Date of joining our Group	Date of appointment as Director	Roles and responsibilities
Mr. Liu Yuanchong (劉元沖)	[59]	Non-executive Director	December 30, 2013	June 22, 2020	Providing strategic advice and recommendations on the operations and management of our Group
Ms. Li Li (李莉)	[48]	Non-executive Director	June 22, 2020	June 22, 2020	Providing strategic advice and recommendations on the operations and management of our Group
Mr. Chen Jie (陳杰)	[50]	Non-executive Director	January 25, 2021	January 25, 2021	Providing strategic advice and recommendations on the operations and management of our Group
Independent non-executive Directors					
Mr. Liu Zhengjun (劉正軍)	[64]	Independent non-executive Director	March 23, 2021	March 23, 2021	Supervising and providing independent advice on the operations and management of our Group
Mr. Shi Luwen (史錄文)	[59]	Independent non-executive Director	March 23, 2021	March 23, 2021	Supervising and providing independent advice on the operations and management of our Group
Mr. Dai Jixiong (戴繼雄)	[63]	Independent non-executive Director	March 23, 2021	March 23, 2021	Supervising and providing independent advice on the operations and management of our Group

Executive Directors

Ms. Jiang Hua (姜華), aged [44], was appointed as our Director on June 22, 2020 and re-designated as our executive Director on March 25, 2022. Ms. Jiang is the chairlady and chief executive officer of our Company and the sole director of Boan Nanjing. She is responsible for overseeing the corporate management, strategic and business development of our Group and overseeing our Board.

Ms. Jiang has over [23] years of experience in the pharmaceutical industry in the PRC. Prior to joining our Group, from September 1998 to September 2020, she worked at the Luye Group with her last position as vice president, where she was primarily responsible for the Luye Group's investment, strategy and business development and investor relations management.

Ms. Jiang obtained a bachelor's degree in economics from Fudan University in the PRC in July 1998. She also obtained a master's degree in business administration from KEDGE Business School (formerly known as Euromed Marseille Ecole de Management) in France in May 2007 and a doctor's degree in business administration from United Business Institutes in Belgium in June 2012. She also obtained a qualification of economist (經濟師) issued by Ministry of Human Resources and Social Security of the PRC (formerly known as Ministry of Personnel of the PRC) in November 2003.

Upon [**REDACTED**], assuming that the [**REDACTED**] is not exercised at all, Ms. Jiang will be interested in [**REDACTED**]% of the total Shares of our Company, which are held on her behalf by the ESOP Entities.

Dr. Dou Changlin (竇昌林), aged [59], was appointed as our Director on November 16, 2019 and re-designated as our executive Director on March 25, 2022. Dr. Dou joined our Company in December 2013 and was responsible for the preliminary set up of our Company and its technological platforms. He is currently our president of R&D, chief operating officer and the sole director of Boan Boston. He is responsible for formulating the R&D and product line development strategies, implementing the R&D activities and overseeing the management of drug development processes of our Group.

Dr. Dou has over [24] years of experience in the pharmaceutical industry, including biopharmaceutical R&D, manufacturing and quality management in various multinational companies. Prior to joining our Group, from September 1995 to November 1999, he worked at Memorial Sloan Kettering Cancer Center, a leading cancer research and treatment center in the U.S., where he was primarily responsible for research in neuroscience and developmental biology. From November 1999 to December 2005, he worked at Regeneron Pharmaceuticals, Inc., a biotechnology company principally engaged in life-transforming medicines in the U.S., where he was primarily responsible for R&D in antibody and recombinant protein drugs including key products such as Eylea®, leading high expression technology development and was the inventor for two patents granted in the U.S.. From February 2006 to November 2007, he served as a group leader at Genentech, a biotechnology company that is now a subsidiary of the Roche Group in the U.S., where he was primarily engaged in the R&D of antibody drugs and innovative antibody production technologies. From December 2007 to March 2009, he

served as a group leader at Invitrogen Corporation, a biotechnology company in the U.S., where he was primarily responsible for the R&D of stable cell line technology and early stage development of therapeutic protein products. He also served as a group leader at Cellular Dynamics International, a leading developer and manufacturer of human cells used in drug discovery, toxicity testing, stem cell banking and cell therapy development in the U.S., where he was primarily responsible for leading the R&D of cell technologies. From July 2011 to June 2012, he last served as a chief technical officer at A-Bio Pharma Pte. Ltd, a biologic contract manufacturing organization (CMO) principally engaged in research, process development and manufacturing service contracting in Singapore, where he was primarily responsible for formulating and implementing the R&D activities and strategic development of the company. From July 2012 to December 2013, he served as a director of biotechnology at the Luye Group, where he was primarily responsible for the strategic development and product planning of the Luye Group's R&D in biopharmaceutical drugs.

Dr. Dou obtained a bachelor's degree in biology from Peking University in the PRC in July 1984. He also obtained a master's degree from the Institute of Neuroscience of the Chinese Academy of Sciences (中國科學院神經科學研究所) (formerly known as Shanghai Brain Research Institute of the Chinese Academy of Sciences (中國科學院上海腦研究所)) in the PRC in March 1988 and a doctor's degree from the State University of New York at Stony Brook in the U.S. in December 1995.

Dr. Dou is the inventor of 18 invention patents for innovative antibody drug candidates and production methods, of which four of them have been successfully granted and the remainder are under review. He has also co-authored a number of scientific publications in journals and the following table is a summary of Dr. Dou's selected publications as the corresponding author in 2021:

Article	Journal	Article Date
Structure and function analysis of a potent human neutralizing antibody CA521^{FALA} against SARS-CoV-2[1]	Communications Biology journal published by Nature Portfolio	April 23, 2021
Two novel human anti-CD25 antibodies with antitumor activity inversely related to their affinity and in vitro activity[2]	Scientific Reports journal published by Nature Portfolio	November 25, 2021

Notes:

1 Song, D., Wang, W., Dong, C. *et al.* Structure and function analysis of a potent human neutralizing antibody CA521^{FALA} against SARS-CoV-2. *Commun Biol* **4,** 500 (2021).

2 Song, D., Liu, X., Dong, C. *et al.* Two novel human anti-CD25 antibodies with antitumor activity inversely related to their affinity and in vitro activity. *Sci Rep* **11,** 22966 (2021).

Upon [**REDACTED**], assuming that the [**REDACTED**] is not exercised at all, Dr. Dou will be interested in [**REDACTED**]% of the total Shares of our Company, which are held on his behalf by the ESOP Entities.

Non-executive Directors

Dr. Li Youxin (李又欣), aged [60], was appointed as our Director on June 22, 2020 and re-designated as our non-executive Director on March 25, 2022. Dr. Li is the vice chairman of our Board. He is responsible for providing strategic advice and recommendations on the operations and management of our Group.

Dr. Li has many years of experience in drug development and the pharmaceutical industry. Prior to joining our Group, from 1991 to 1993, he served as a research fellow of Alexandar von Humboldt Foundation of University of Marburg in Germany. He served as a senior researcher of the drug manufacturing department at Sanofi-Aventis (formerly known as Hoechst AG), a multinational pharmaceutical and healthcare company based in Germany, where he was primarily responsible for R&D and drug discovery. He also served as a senior scientist officer at Schwarz Pharma AG, a medical and pharmaceutical company in Germany.

Dr. Li joined the Luye Group in October 2007 and has been serving in various roles with his latest position as the chairman of the science and technology committee since April 2022. From October 2007 to March 2022, he served as the senior vice president and head of R&D of the Luye Group, where he was primarily responsible for a number of Luye Group's R&D platforms including its long-acting and extended release technology and targeted drug delivery platforms. Since June 2008, he has been serving as a professor of pharmacy at the College of Life Sciences of Jilin University in the PRC.

Dr. Li obtained a bachelor's degree in chemistry, master's degree and doctor's degree from Peking University in the PRC in July 1982, July 1985 and July 1988, respectively.

Upon [**REDACTED**], assuming that the [**REDACTED**] is not exercised at all, Dr. Li will be interested in [**REDACTED**]% of the total Shares of our Company, which are held on his behalf by the ESOP Entities.

Mr. Liu Yuanchong (劉元沖), aged [59], was appointed as our Director on June 22, 2020 and re-designated as our non-executive Director on March 25, 2022. Mr. Liu joined our Group in December 2013 and is responsible for providing strategic advice and recommendations on the operations and management of our Group.

Mr. Liu Yuanchong has over [34] years of experience in accounting and audit. Prior to joining our Group, from 1980 to 1983, he worked at Shandong Laiyang Biochemical Pharmaceutical Factory (山東萊陽生物製藥廠). From September 1983 to September 1986, he served as a teacher at Yantai Business Vocational Secondary School (煙台商業中專), a secondary school in the PRC. He also served as the head of accounting at Yantai Alternator Plant (煙台家電交電總公司). Since March 1997, he has served in various positions in the Luye Group, with his latest position as the chief financial officer of the Luye Group, where he is primarily responsible for the overall financial management of the Luye Group.

Since November 2010, Mr. Liu has served as a director of Beijing Peking University WBL Biotech Co., Ltd (北京北大維信生物科技有限公司), a joint-venture company set up by the Luye Group and Peking University principally engaged in R&D, production and sale of modern Chinese medicine, where he is primarily responsible for advising on the company's business and investment plans. Since February 2020, he has served as a director of Shandong Asj Biotechnology Co., Ltd. (山東愛士津生物技術有限公司), a company principally engaged in manufacturing biological products in the PRC, where he is primarily responsible for advising on the company's business and investment plans.

Mr. Liu obtained an associate degree in commercial economics from Shandong Institute of Commerce and Technology (山東商業職業技術學院) (formerly known as Shandong Vocational University of Commerce (山東省商業職工大學)) in the PRC in September 1989. He also obtained a postgraduate certificate in financial management from Peking University in the PRC in October 2006. He obtained an accountant qualification issued by the Ministry of Human Resources and Social Security of the PRC (formerly known as the Ministry of Personnel of the PRC) and the Ministry of Finance of the PRC in November 1993.

Mr. Liu was a supervisor of Shanghai Langhe Pharmaceutical Technology Co., Ltd. (上海朗和醫藥科技有限公司) ("**Shanghai Langhe**"), a company established in the PRC on January 10, 2003. As Shanghai Langhe has ceased to carry on its business operations, on April 17, 2013, the business license of Shanghai Langhe was revoked. Mr. Liu confirmed that, to the best of his knowledge and belief, Shanghai Langhe was solvent as at the time when its business license was revoked and as of the Latest Practicable Date, no claims had been made against him and he was not aware of any actual or potential claim that has been or will be made against him as a result of the revocation of license of Shanghai Langhe.

Upon [**REDACTED**], assuming that the [**REDACTED**] is not exercised at all, Mr. Liu will be interested in [**REDACTED**]% of the total Shares of our Company, which are held on his behalf by the ESOP Entities.

Ms. Li Li (李莉), aged [48], was appointed as our Director on June 22, 2020 and re-designated as our non-executive Director on March 25, 2022. She is responsible for providing strategic advice and recommendations on the operations and management of our Group.

Ms. Li has over [24] years of experience in the pharmaceutical industry. Prior to joining our Group, since July 1997, she has served in various positions in the Luye Group, with her latest position as a vice president of the Luye Group, where she is primarily responsible for overseeing and managing the administration, human resources and public relations function of the Luye Group.

Since February 2020, she has been serving as a director at Shandong Asj Biotechnology Co., Ltd. (山東愛士津生物技術有限公司), a company principally engaged in the production of biological products in the PRC, where she is primarily responsible for providing strategic development advice, selecting and overseeing the performance of directors and senior management. Since November 2020, she has been serving as a director at Guangzhou Patronus Biotechnology Co., Ltd. (廣州派諾生物技術有限公司), a scientific research company in the PRC, where she is primarily responsible for providing strategic development advice, selecting and overseeing the performance of directors and senior management.

Ms. Li obtained a bachelor's degree in biochemistry from Yantai University in the PRC in July 1997. She also completed a postgraduate course in applied psychology and human resources management and development at Institute of Psychology of Chinese Academy of Sciences (中國科學院心理研究所) in the PRC in February 2009 and obtained a master's degree in business administration from China Europe International Business School (中歐國際工商學院) in the PRC in August 2021. She also obtained a qualification of Level 2 Human Resource Professional (企業人力資源管理師(二級)) issued by the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部) in December 2004.

Ms. Li was a supervisor of Yantai Botian Biotechnology Co., Ltd. (煙台博天生物科技有限公司) ("**Yantai Botian**"), a company established in the PRC on March 29, 2006. As Yantai Botian has voluntarily ceased its business operations for over six months continuously, on November 10, 2007, the business license of Yantai Botian was revoked. Ms. Li confirmed that, to the best of her knowledge and belief, Yantai Botian was solvent as at the time when its business license was revoked and as of the Latest Practicable Date, no claims had been made against her and she was not aware of any actual or potential claim that has been or will be made against her as a result of the revocation of license of Yantai Botian.

Upon [**REDACTED**], assuming that the [**REDACTED**] is not exercised at all, Ms. Li will be deemed to be interested in [**REDACTED**]% of the total Shares of our Company as she is the general partner of each of the ESOP Entities.

Mr. Chen Jie (陳杰), aged [50], was appointed as our Director on January 25, 2021 and re-designated as our non-executive Director on March 25, 2022. Mr. Chen is responsible for providing strategic advice and recommendations on the operations and management of our Group.

Mr. Chen has over 20 years of managerial experience in consulting, investment and multinational companies. Prior to joining our Group, from September 1995 to May 1999, he last served as a Guangzhou branch general manager at Shell (China) Ltd, a company principally engaged in development and utilization of petroleum and other energy sources in the PRC, where he was primarily responsible for overseeing the group-wide efficiency, quality control and managing the group's affairs. From December 2002 to June 2004, he served as a consultant in AT Kearney (Shanghai) Management Consulting Co., Ltd., a management consulting firm. From October 2004 to April 2006, he served as a business development manager at Eaton (China) Investments Co. Ltd (伊頓(中國)投資有限公司), a company principally engaged in capital investment in the PRC, where he was primarily responsible for mergers and acquisitions and business development. From March 2006 to October 2008, he served as a business manager of professional product at Syngenta (China) Investment Co., Ltd. Shanghai Branch (先正達(中國)投資有限公司上海分公司), a science-based agricultural technology company in the PRC, where he was primarily responsible for overseeing product management. From October 2008 to May 2010, he served as a managing director of CXC Capital, Inc (開投基金), a venture capital firm in the PRC. From June 2010 to April 2012, he served as a senior vice president of GL Capital Group (德福資本), a private equity investment in the PRC. In September 2013, he co-founded SIP Sungent, an investment firm focusing on early and growth stage life science and healthcare investments and one of our Pre-[**REDACTED**] Investors, where he was primarily responsible for investment management. In April 2016, he co-founded Suzhou Yuansheng Private Fund Management Partnership (Limited Partnership) (蘇州元生私募基金管理合伙企業(有限合伙)), a limited partnership which is principally engaged in investment and consulting services, where he was primarily responsible for investment management. From July 2016 to June 2021, he last served as a non-executive director of Kintor Pharmaceuticals Limited, a company principally engaged in developing novel drugs and whose shares are listed on the Stock Exchange (stock code: 9939), where he is primarily responsible for overseeing the corporate development and strategic planning of the group. Since January 2016, he has been serving as a director of Shenzhen Nanomicro Technology Co., Ltd (深圳市納微科技有限公司), a subsidiary of Suzhou Nanomicro Technology Co., Ltd. (蘇州納微科技股份有限公司) and whose shares are listed on the Shanghai Stock Exchange (the "**SSE**") (stock code: 688690), where he is primarily responsible for providing strategic development advice and recommendations on the operations and management of the group. Since June 2021, he has served as an independent director of Sichuan Kelun Pharmaceutical Co., Ltd. (四川科倫藥業股份有限公司), a company principally engaged in manufacturing pharmaceutical products and whose shares are listed on the Shenzhen Stock Exchange (stock code: 002422), where he is primarily responsible for providing independent advice to the Board.

Mr. Chen obtained a bachelor's degree in business management from Sun Yat-sen University in the PRC in June 1995. He also obtained a master's degree in business administration from Cornell University in the U.S. in May 2002.

Mr. Chen was a director of Shanghai Gongsheng Business Consulting Co., Ltd. (上海共勝商務諮詢有限公司) ("**Shanghai Gongsheng**"), a company established in the PRC on September 27, 2006. As Shanghai Gongsheng has ceased to carry on its business operations, on June 7, 2017, the business license of Shanghai Gongsheng was revoked. Mr. Chen confirmed that, to the best of his knowledge and belief, Shanghai Gongsheng was solvent as at the time when its business license was revoked and as of the Latest Practicable Date, no claims had been made against him and he was not aware of any actual or potential claim that has been or will be made against him as a result of the revocation of license of Shanghai Gongsheng.

Independent non-executive Directors

Mr. Liu Zhengjun (劉正軍), aged [64], was appointed as our independent Director on March 23, 2021 and re-designated as our independent non-executive Director on March 25, 2022. He is responsible for supervising and providing independent advice on the operations and management of our Group.

Mr. Liu has over [27] years of experience in the capital markets industry. Prior to joining our Group, from December 1996 to August 2018, he worked at and last served as a senior manager at the SSE, where he as primarily responsible for policy research, company listing service and supervision of issuance and underwriting. Since November 2018, he has been serving as an independent director of Winsan (Chengdu) Medical Science and Technology Co., Ltd. (運盛(成都)醫療科技股份有限公司) (formerly known as Winsan (Shanghai) Medical Science and Technology Co., Ltd (運盛(上海)醫療科技股份有限公司)), a company principally engaged in technology development, technical consultation, technical service, medical equipment operation in the public health and regional medical information in the PRC and whose shares are listed on the SSE (stock code: 600767), where he was primarily responsible for conducting research and providing recommendations for the company's investments and development strategies. Since April 2020, he has been serving as an independent director of Nancal Technology Co., Ltd (能科科技股份有限公司), a company principally engaged in smart manufacturing and smart electrical advanced technology in the PRC and whose shares are listed on the SSE (stock code: 603859), where he was primarily responsible for conducting research and providing recommendations for the company's investments and development strategies and overseeing the standards and procedures for the selection of the company's directors and senior management.

Mr. Liu graduated with a bachelor's qualification in law from East China University of Political Science and Law in the PRC in July 2004. He obtained an economist qualification issued by the Qualification Evaluation Committee for Economic Series Intermediate Professional and Technical Positions of SHFETC (上海外經貿委經濟系列中級專業技術職務任職資格評審委員會) in October 1992 and a Level 2 Certificate of Psychological Consultant (二級心理諮詢師) from Shanghai Vocational Skills Appraisal Center (上海市職業技能鑒定中心) in July 2005. He also obtained a Board Secretary Qualification Certificate from the SSE in July 2018 and an independent director qualification certificate from the SSE in August 2018.

Mr. Shi Luwen (史錄文), aged [59], was appointed as our independent Director on March 23, 2021 and re-designated as our independent non-executive Director on March 25, 2022. He is responsible for supervising and providing independent advice on the operations and management of our Group.

Mr. Shi has over [35] years of experience in the pharmaceutical industry. Prior to joining our Group, since July 1987, he has been working at the School of Pharmaceutical Sciences of Peking University (北京大學藥學院) with his latest position as a professor in pharmaceutical administration and clinical pharmacy. Since 2002, he has been serving as a director of the International Research Center for Medical Administration of Peking University (北京大學醫藥管理國際研究中心). From December 2015 to December 2021, he served as an independent director of China Meheco Group Co., Ltd (中國醫藥健康產業股份有限公司), a company principally engaged in distribution of pharmaceutical and health care products in the PRC and whose shares are listed on the SSE (stock code: 600056), where he was primarily responsible for providing independent advice to the company. From May 2017 to July 2020, he served as a director of Zhejiang CONBA Pharmaceutical Co., Ltd (浙江康恩貝製藥股份有限公司), a company principally engaged in the R&D, manufacture and distribution of traditional Chinese medicines, modern phytomedicines and chemical drugs in the PRC and whose shares are listed on the SSE (stock code: 600572), where he was primarily responsible for providing independent advice to the company. Since December 2016, Mr. Shi has served as an independent non-executive director of Hospital Corporation of China Limited (弘和仁愛醫療集團有限公司), a company principally engaged in operation and management of hospitals and whose shares are listed on the Stock Exchange (stock code: 3869), where he has been primarily responsible for providing independent opinion and judgment to the board. Since June 2020, he has been serving as an independent non-executive director of Dragon Laboratory Instruments Limited (大龍興創實驗儀器(北京)股份公司), a company principally engaged in manufacturing laboratory instruments in the PRC, where he is primarily responsible for providing independent advice to the company.

Mr. Shi obtained a bachelor's degree in chemistry from Peking University Health Science Center (北京大學醫學部) (formerly known as Peking Medical University (北京醫科大學)) in the PRC in July 1987. He also obtained a master's degree in health professions education from the University of Illinois in the U.S. in July 1992. He obtained an independent director qualification certificate from the SSE in January 2016.

In November 2010, Mr. Shi was awarded the Xue Muqiao Price Research Award (薛暮橋價格研究獎) by the Price Association of China (中國價格協會). In June 2012, he was awarded the Scientific Chinese Person (2011) (科學中國人(2011)年度人物) by Scientific Chinese Magazine. In December 2018, he was awarded the Most Concerned Medical Reform Experts (2018年度最受關注醫改專家) by Health News (健康報).

Mr. Dai Jixiong (戴繼雄), aged [63], was appointed as our independent Director on March 23, 2021 and re-designated as our independent non-executive Director on March 25, 2022. He is responsible for supervising and providing independent advice on the operations and management of our Group.

Mr. Dai has over [31] years of experience in accounting and audit. Prior to joining our Group, from January 1986 to October 2004, he served in various positions such as deputy supervisor of the research office, associate professor and postgraduate tutor at Shanghai University of Finance and Economics. From May 2006 to December 2013, he last served as the deputy financial controller and general manager of the finance department at Donghao Lansheng (Group) Co., Ltd. (東浩蘭生(集團)有限公司) (formerly known as Shanghai Lansheng (Group) Corporation (上海蘭生(集團)有限公司)), a state-owned company mainly engaged in international trade in the PRC, where he was primarily responsible for financial and accounting management. From December 2013 to June 2019, he served in various positions such as deputy general manager and chief financial officer at Shanghai Minmetals Development Ltd (上海五金礦產發展有限公司), a company principally engaged in import and export trade in the PRC, where he was primarily responsible for formulating the company's accounting, audit, financial management and risk management and controls.

Since October 2019, Mr. Dai has been serving as an independent director of Bestechnic (shanghai) Co., Ltd (恒玄科技(上海)股份有限公司), a company principally engaged in developing, manufacturing and selling intelligent audio system on chip (SoC) products whose shares are listed on the SSE (stock code: 688608). Since December 2020, he has been serving as an independent director of Shanghai Anlogic Infotech Co., Ltd (上海安路信息科技股份有限公司), a company principally engaged in the R&D, design, and sales of integrated circuits whose shares are listed on the SSE (stock code: 688107). Since March 2021, he has been serving as an independent director of Shanghai Magnity Electronics Co., Ltd (上海巨哥科技股份有限公司), a company principally engaged in the R&D of thermal imaging technologies. Since February 2022, he has also been serving as an independent director of Jinzhou Jixiang Molybdenum Co Ltd. (錦州吉翔鉬業股份有限公司), a company principally engaged in the production, processing and sales of molybdenum products whose shares are listed on the SSE (stock code: 603399).

Mr. Dai obtained a bachelor's degree in economics from Shanghai University of Finance and Economics (previously known as Shanghai Institute of Finance and Economics) in the PRC in July 1983. He also obtained a master's degree in economics from Shanghai University of Finance and Economics in the PRC in March 1986. He has been a member of Shanghai Institute of Certified Public Accountants since December 2009. He obtained an independent director qualification certificate from the SSE in October 2014. He has obtained a senior accountant (正高級會計師) qualification issued by Shanghai Municipal Human Resources and Social Security Bureau (上海市人力資源和社會保障局) since September 2017. He has been awarded as a Shanghai Outstanding Accountant (上海市先進會計工作者) by Shanghai Municipal Finance Bureau (上海市財政局) in August 2009.

SUPERVISORS

In accordance with the PRC Company Law, all joint stock companies are required to establish a supervisory committee, which is responsible for supervising the Board and senior management on fulfilling their respective duties, financial performance, internal control management and risk management of the corporation. Our supervisory committee consists of three members comprising one employee representative Supervisor and two Supervisors representing Shandong Luye.

The detailed information of our Supervisors are listed below.

Name	Age	Existing position(s) in our Group	Date of joining our Group	Date of appointment as Supervisor	Roles and responsibilities
Ms. Zhang Xiaomei (張曉玫)	[52]	Supervisor and chairlady of our supervisory committee	December 13, 2017	December 13, 2017	Supervising the overall operation of the Supervisory Committee and our Board, senior management and the financial management of our Group
Ms. Ning Xia (寧夏)	[34]	Employee representative Supervisor and human resources supervisor	October 1, 2020	March 23, 2021	Supervising and providing independent advice to the Board and overseeing our company's human resources department
Ms. Liu Xiangjie (劉祥杰)	[50]	Supervisor	March 23, 2021	March 23, 2021	Supervising and providing independent advice to the Board

Ms. Zhang Xiaomei (張曉玫), aged [52], was appointed as our Supervisor on December 13, 2017 and re-designated as chairlady of our supervisory committee on March 23, 2021. She is responsible for supervising the overall operation of the supervisory committee, our Board, senior management and the financial management of our Group.

Ms. Zhang has over [28] years of experience in the accounting and audit industry. Prior to joining our Group, from April 1994 to June 2009, she last served as the chief accountant of a subsidiary of Yantai Yuancheng Enterprise Co., Ltd (煙台園城企業股份有限公司) (formerly known as Yantai Hualian Development Group (煙台華聯發展集團)), a company principally engaged in the retail industry in the PRC and whose shares are listed on the SSE (stock code: 600766), where she was primarily responsible for overseeing the company's auditing and financial management. Since July 2009, Ms. Zhang has served as a financial controller of Luye Investment Group Co., Ltd. (綠葉投資集團有限公司), where she is primarily responsible for formulating and implementing the company's auditing and financial management.

Ms. Zhang graduated with a bachelor's qualification in accounting from Shandong University of Finance and Economics (山東財經大學) (formerly known as Shandong Institute of Economics (山東經濟學院)) in July 2004. She obtained an accountant (會計師) qualification issued by the Ministry of Finance of the PRC (中華人民共和國財政部) in May 1997, chief financial officer certificate (財務總監證書) issued by China Enterprise Confederation (中國企業聯合會) in March 2006 and chief financial officer certificate (財務總監(CFO)崗位證書) from China Certification Center of University of Cambridge Vocational/Professional Qualification (劍橋大學職業/專業資格中國認證中心) in September 2010. She has also obtained the Certified Tax Planner (註冊高級納稅籌劃師) qualification issued by The Educational Specialist Committee of China Science and Technology Institute Center (中國科學技術協會教育專家委員會) in October 2012, senior financial management technician of CIE professional leadership (CIE職業領導之財務管理高級技師) from the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部) in November 2013 and senior management accountant (管理會計師) qualification certified by Beijing National Accounting Institute (北京國家會計學院) in August 2018.

Ms. Ning Xia (寧夏), aged [34], was appointed as our Supervisor on March 23, 2021. Ms. Ning joined our Group in October 2020 and is our human resources supervisor. She is responsible for supervising and providing independent advice to the Board.

Ms. Ning has over [12] years of experience in the pharmaceutical industry. Prior to joining our Group, from January 2011 to July 2011, she served as a manufacturing technologist of Shanghai Xinyi Pharmaceutical Co., Ltd. (上海信誼藥廠有限公司), a pharmaceutical company in the PRC, where she was primarily responsible for drug production and manufacturing. From October 2011 to February 2012, she served as a quality auditor at Nanjing Luye Sike Pharmaceutical Co., Ltd. (南京綠葉思科藥業有限公司), a company principally engaged in the R&D, production and sales of cancer drugs in the PRC, where she was primarily responsible for supervising and managing workshop production and quality control. From March 2012 to July 2018, she last served as a human resources business partner (HBRP) manager of Nanjing Sanhome Pharmaceutical Limited Company (南京聖和藥業股份有限公司), a pharmaceutical company in the PRC. From August 2018 to June 2019, she served in the human resources department of Realcan Pharmaceutical Co., Ltd. (瑞康醫藥股份有限公司), a company principally engaged in wholesale and distribution of pharmaceutical products in the PRC. From July 2019 to September 2020, she served as a human resources business partner at Yantai Rongchang Pharmaceuticals, Ltd. (煙台榮昌製藥股份有限公司), a company principally engaged in the R&D, manufacturing and sales of small molecule and biological drugs in the PRC, where she was primarily responsible for management of human resources in the sales department.

Ms. Ning obtained a bachelor's degree in pharmacy from Shenyang Pharmaceutical University (瀋陽藥科大學) in the PRC in July 2010. She obtained an assistant engineer (助理工程師) certification issued by Nanjing Leader Group Office for Professional Qualifications (南京市職稱(職業資格)工作領導小組辦公室) in July 2012 and Level 3 Enterprise Human Resource Manager (企業人力資源管理師(三級)) by the Occupational Skills Testing Authority of the Ministry of Human Resources and Social Security of PRC (人社部職業技能鑒定中心) in June 2014.

Ms. Liu Xiangjie (劉祥杰), aged [50], was appointed as our Supervisor on March 23, 2021. She is responsible for supervising and providing independent advice to the Board.

Ms. Liu has over [29] years of experience in the finance and accounting industry. Prior to joining our Group, since August 1994, she served in various positions in the Luye Group with her latest position as the financial director of Shandong Luye, where she is primarily responsible for overseeing and supervising the financial management of the company.

Ms. Liu obtained a vocational secondary school degree in industrial enterprise management from Yantai Industrial School (山東省煙台工業學校) in the PRC in July 1994. She also graduated from Shandong Cadres Correspondence University (山東幹部函授大學) in the PRC with a junior college diploma in finance and accounting in June 1997. She has obtained an Intermediate Accountant (中級會計師) certification issued by the Human Resources and Social Security Department of Shandong Province (山東省人力資源和社會保障廳) since December 2015 and a certified management accountant (註冊管理會計師) certification by the Institute of Management Accountants since July 2018. She has also obtained an International Certified Public Accountants qualification certified by American Association of Chartered Accountants since September 2020 and a Senior Management Accountant (高級管理會計師) qualification certified by Beijing National Accounting Institute (北京國家會計學院) since October 2020.

SENIOR MANAGEMENT

The table below sets forth the key information of our senior management:

Name	Age	Existing position(s) in our Group	Date of joining our Group	Date of appointment as senior management	Roles and responsibilities
Mr. Wang Shenghan (王盛翰)	[43]	Chief financial officer	September 1, 2020	September 1, 2020	Overseeing, advising and implementing comprehensive financial and strategies of our Group
Mr. Chi Guangming (池廣明)	[57]	Vice president of business operations center	April 1, 2021	March 25, 2022	Formulating sales strategies and operational management for marketing of our Group
Mr. Lu Jun (盧軍)	[56]	Senior vice president and head of biotechnology engineering center and quality department	March 9, 2015	March 25, 2022	Overseeing and managing the operations of our Company's biotechnology engineering center and quality department
Mr. Song Deyong (宋德勇)	[40]	Head of biologics discovery department	December 1, 2015	March 25, 2022	Managing our Company's biopharmaceutical target research, projects selection, biopharmaceutical molecules discovery and lead molecules confirmation

Mr. Wang Shenghan (王盛翰) (formerly known as Wang Dongdong (王冬冬)), aged [43], joined our Group in September 2020 as the chief financial officer of our Company. He is responsible for overseeing, advising and implementing comprehensive financial and strategies of our Group.

Mr. Wang joined the Luye Group in December 2009. From December 2009 to August 2020, he served as the assistant to the president and later the director of investment and business development of Luye Pharma, where he was responsible for securities affairs, investment and capital operations.

Mr. Wang has over [20] years of experience in accounting and corporate finance. Prior to joining our Group, from July 2001 to May 2004, he served as an audit manager at Tianyuanquan Accounting Firm (Special General Partnership) (天圓全會計事務所(特殊普通合伙)) (formerly known as Beijing Tianyuanquan Accounting Firm (Special General Partnership) (北京天圓全會計事務所(特殊普通合伙)), whose predecessor is Shandong Qianju Accounting Firm (山東乾聚會計師事務所)), an accounting firm in the PRC. From June 2004 to July 2008, he last served as a deputy general accountant at Yantai Yuancheng Enterprise Co., Ltd (煙台園城企業股份有限公司), a company principally engaged in the retail industry in the PRC and whose shares are listed on the SSE (stock code: 600766), where he was primarily responsible for managing the annual accounting and auditing of the company. From October 2008 to November 2009, he served as the financial controller and secretary of the board at Qingdao Tianren Huanjing Co., Ltd (青島天人環境股份有限公司), a company mainly engaged in biomass energy development, environmental protection and new energy projects in the PRC, where he was primarily responsible for the listing application, investment and capital operations. Since November 2016, he has been serving as a director of Shandong Luye Natural Medicine R&D Co., Ltd. (山東綠葉天然藥物研究開發有限公司), a company principally engaged in the R&D in natural medicine in the PRC. Since January 2021, he has been serving as a director of Yantai Luye Hospital Management Co., Ltd. (煙台綠葉醫院管理有限公司), a company principally engaged in biomedicine healthcare, marine biology and bio-agriculture investments in the PRC, where he is primarily responsible for providing strategic development, finance and investment advice.

Mr. Wang obtained a bachelor's degree of economics in finance from Shandong University of Finance and Economics (山東財經大學) (formerly known as Shandong Institute of Economics (山東經濟學院)) in the PRC in July 2001. He also obtained a master's degree in business administration from Ocean University of China (中國海洋大學) in the PRC in January 2010. He obtained a certified public accountant qualification issued by Shandong Institute of Certified Public Accountants (山東省註冊會計師協會) in the PRC in January 2008.

Mr. Chi Guangming (池廣明), aged [57], joined our Group as the vice president of the business operations center of our Company in April 2021. He is responsible for formulating sales strategies and the operational management for marketing of our Group.

Mr. Chi has over [31] years of experience in the pharmaceutical industry. Prior to joining our Group, from September 1990 to March 1997, Mr. Chi served as an attending physician in internal medicine at Taipusi Hospital (太僕寺旗醫院), a hospital in Inner Mongolia in the PRC. From April 1997 to December 2007, he last served as a regional manager at Shandong Luye, where he was primarily responsible for managing the sales and marketing in northern China. From January 2008 to March 2021, he served as a sales director of Nanjing Luye, where he was primarily responsible for supervising and managing the sales of Nanjing Luye.

Mr. Chi obtained a bachelor's degree in medicine from College of Traditional Mongolian Medicine of Inner Mongolia Minzu University (內蒙古民族大學蒙醫藥學院) (formerly known as Inner Mongolia College of Traditional Mongolian Medicine (內蒙古蒙醫學院)) in the PRC in July 1990. He also graduated from an executive master's degree in business administration program from Renmin University of China (中國人民大學) in the PRC in January 2003. He was qualified as an associate chief physician (副主任醫師) specializing in internal medicine by the Human Resources and Social Security Department of Inner Mongolia Autonomous Region (內蒙古自治區人力資源和社會保障廳) (formerly known as Personnel Department of Inner Mongolia Autonomous Region (內蒙古自治區人事廳)) in July 2007.

Mr. Lu Jun (盧軍), aged [56], joined our Group in March 2015 and was appointed as our senior vice president and head of biotechnology engineering center and quality department in January 2021. He is responsible for overseeing and managing the operations of our Company's biotechnology engineering center and quality department.

Mr. Lu has over [21] years of experience in the pharmaceutical industry. Prior to joining our Group, he served as a supervisor of the process science department at Eli Lilly and Company for over five years, a company principally engaged in drug manufacturing in the U.S., where he was primarily responsible for the R&D and industrial purification processes for several marketed drugs. From March 2004 to June 2006, he served as a senior process engineer at Cubist Pharmaceuticals Inc., a company principally engaged in R&D and commercializing biopharmaceutical products, where he was primarily responsible for managing the R&D for industrial design and commercialization production processes for new drugs. From July 2006 to March 2013, he served as a senior manager of process development at Ipsen Bioscience, Inc. (formerly known as Biomeasure Inc.), a company principally engaged in R&D of engineered peptides and proteins for human therapeutics in the U.S., where he was primarily responsible for managing the process characterization and validation, GMP commercial production support and biologics license application (BLA) for a new autonomous bioengineered drug. From April 2013 to March 2015, he served as an associate director at Momenta Pharmaceutical Inc. in the U.S., a company principally engaged in discovering and developing novel therapies for immune-mediated diseases.

Mr. Lu obtained a bachelor's degree in cell biology and genetics from Peking University in the PRC in July 1988. He further obtained a master's degree in biochemistry and molecular biology from University of Southern California in the U.S. in December 1997 and a master's degree in business administration from University of Chicago in the U.S. in June 2003.

Mr. Song Deyong (宋德勇), aged [40], joined our Group in December 2015 and was appointed as our head of biologics discovery department in January 2022. He is responsible for managing our Company's biopharmaceutical target research, projects selection, biopharmaceutical molecules discovery and lead molecules confirmation.

Mr. Song has over [13] years of experience in the biopharmaceutical industry. Prior to joining our Group, from April 2009 to December 2009, Mr. Song served as a research staff at Beijing ABT Gene Engineering Technology Co., Ltd (北京安波特基因工程技術有限公司), a company principally engaged in the R&D of genetic engineering antibody drugs and technical services in the PRC, where he was primarily responsible for R&D of genetic engineering antibody drugs and providing genetic engineering technical services. From December 2009 to November 2015, he last served as a supervisor at Sinocelltech Group Limited (北京神州細胞生物技術集團股份公司) (formerly known as Beijing Sino Biotechnology Co., Ltd (北京義翹神州生物技術有限公司)), a company principally engaged in developing and manufacturing recombinant proteins, monoclonal antibodies, and vaccines in the PRC, where he was primarily responsible for optimizing antibody discovery technologies, screening mouse and rabbit monoclonal antibodies and conducting biological evaluation of monoclonal antibodies.

Mr. Song obtained a bachelor's degree in biology and a master's degree in microbiology from Shandong University (山東大學) in the PRC in July 2005 and June 2008, respectively.

OTHER INFORMATION IN RELATION TO OUR DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Save as disclosed above, each of our Directors and Supervisors has confirmed that there are no other matters relating to his/her appointment as a Director that need to be brought to the attention of our Shareholders and there is no other information in relation to his appointment which is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules.

Save as disclosed in this document, none of our Directors, Supervisors and senior management hold any other positions within our Group.

Save as disclosed above, none of our Directors, Supervisors and senior management has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this document.

None of our Directors, Supervisors and senior management is related to other Directors, Supervisors and senior management.

COMPANY SECRETARY

Ms. Lai Siu Kuen (黎少娟), was appointed as our company secretary on March 10, 2022. Ms. Lai currently serves as a director of corporate services of Tricor Services Limited, a corporate service provider in Hong Kong and is well experienced in advising and assisting with the corporate secretarial and corporate governance matters of Hong Kong listed companies. She is currently the sole/joint company secretary(ies) of several companies whose shares are listed on the Stock Exchange, including CGN Mining Company Limited (stock code: 1164), Pujiang International Group Limited (stock code: 2060), Shanghai Junshi Biosciences Co., Ltd. (stock code: 1877), Yangtze Optical Fiber and Cable Joint Stock Limited Company (stock code: 6869).

Ms. Lai holds a bachelor's degree in accounting and is a fellow member of both The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom.

BOARD COMMITTEES

Our Board has established the Audit Committee, the Remuneration Committee, the Nomination Committee and the Strategy Committee and delegated various responsibilities to these committees, which assist our Board in discharging its duties and overseeing particular aspects of our Group's activities.

Audit Committee

We [have] established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraphs D.3 of the Corporate Governance Code ("**CG Code**") as set out in Appendix 14 to the Listing Rules. The Audit Committee consists of Mr. Liu Yuanchong, our non-executive director, Mr. Dai Jixiong and Mr. Liu Zhengjun, both being our independent non-executive Directors. Mr. Dai Jixiong is the chairperson of the Audit Committee.

The primary duties of the Audit Committee are to (i) review and supervise our financial reporting process and internal control system of our Group, risk management and internal audit; (ii) provide advice and comments to our Board in respect of financial, risk management and internal control matters; and (iii) perform other duties and responsibilities as may be assigned by the Board.

Remuneration Committee

We [have] established the Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of the CG Code as set out in Appendix 14 to the Listing Rules. The Remuneration Committee consists of three members, namely Ms. Li Li, our non-executive director, Mr. Liu Zhengjun and Mr. Dai Jixiong, both being our independent non-executive Directors. Mr. Liu Zhengjun is the chairperson of the Remuneration Committee.

The primary duties of the Remuneration Committee include, but not limited to (i) establishing, reviewing and providing advice to our Board on our policy and structure concerning remuneration of our Directors and senior management and on the establishment of a formal and transparent procedure for developing policies concerning such remuneration; (ii) determining the terms of the specific remuneration package of each Director and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Directors from time to time.

Nomination Committee

We [have] established the Nomination Committee with written terms of reference in compliance with paragraph B.3 of the CG Code as set out in Appendix 14 to the Listing Rules. The Nomination Committee consists of three members, namely Ms. Li Li, our non-executive Director, Mr. Shi Luwen and Mr. Liu Zhengjun, both being our independent non-executive Director. Mr. Shi Luwen is the chairperson of the Nomination Committee.

The primary duties of the Nomination Committee are to (i) review the structure, size and composition of our Board on a regular basis and make recommendations to the Board regarding any proposed changes to the composition of our Board; (ii) identify, select or make recommendations to our Board on the selection of individuals nominated for directorship, and ensure the diversity of our Board members; (iii) perform review on the contributions made by our Directors (including our independent non-executive Directors) and the sufficiency of time devoted to perform their duties; (iv) assess the independence of our independent non-executive Directors; and (v) make recommendations to our Board on relevant matters relating to the appointment, re-appointment and removal of our Directors and succession planning for our Directors.

Strategy Committee

We [have] established the Strategy Committee, which consists of three members, namely Ms. Jiang Hua and Dr. Dou Changlin both being our executive Directors, and Mr. Shi Luwen, our independent non-executive Director. Ms. Jiang Hua is the chairperson of the Strategy Committee. The primary duties of the Strategy Committee are to study and advise on the long term strategy and major development and financing plans of our Group.

CORPORATE GOVERNANCE

Chairlady and chief executive officer

Ms. Jiang Hua, who is one of our executive Directors, will continue to assume the responsibilities as our chairlady and chief executive officer upon [**REDACTED**]. Code provision C.2.1 of the CG Code as set out in Appendix 14 to the Listing Rules states that the roles of the chairman and chief executive officer should be separate and should not be performed by the same individual. Our Board believes that Ms. Jiang Hua should continue to assume the responsibilities of chief executive officer upon [**REDACTED**] as this arrangement will improve the efficiency of our decision-making and execution process given her knowledge of our Group's affairs. Further, our Company has put in place an appropriate check-and-balance mechanism through our Board and our independent non-executive Directors. In light of the above, our Board considers that the deviation from Code provision C.2.1 of the CG Code is appropriate in the circumstances of our Company.

Board diversity policy

Our Board has adopted a board diversity policy which sets out the approach to achieve diversity on our Board. Our Company recognizes and embraces the benefits of having a diverse Board and sees increasing diversity at the Board level as an essential element in supporting the attainment of our Company's strategic objectives and sustainable development. Our Company seeks to achieve Board diversity through the consideration of a number of factors, including but not limited to talent, skills, gender, age, cultural and educational background, ethnicity, professional experience, independence, knowledge and length of service. We will select potential Board candidates based on merit and his/her potential contribution to our Board while taking into consideration our own business model and specific needs from time to time. All Board appointments will be based on meritocracy and candidates will be considered against objective criteria, having due regard to the benefits of diversity on our Board.

Our Board has a balanced mix of knowledge, skills and experience, including but without limitation to the pharmaceutical, accounting, finance, corporate finance and capital markets industry. Members of our Board have obtained degrees in various majors including biology, chemistry, biochemistry, economics, business administration, financial management, applied psychology and human resources management, business management, law and health professions. We have three independent non-executive Directors from different industry backgrounds, including accounting, pharmaceutical and capital markets industry. Furthermore, our Directors are of a wide range of age, from [44] years old to [63] years old.

With regards to gender diversity on the Board, we recognize the particular importance of gender diversity. Our Board currently comprises two female Directors and seven male Directors. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. Our board diversity policy provides that our Board should aim to increase the proportion of female members over time after [**REDACTED**] where possible when selecting and making recommendations on suitable candidates for Board appointments. We will also ensure that there is gender diversity when recruiting staff at mid to senior level so that we will have a pipeline of female senior management and potential successors to our Board going forward. It is our objective to maintain an appropriate balance of gender diversity with reference to the expectations of stakeholders and international and local recommended best practices.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After [**REDACTED**], our Nomination Committee will review our board diversity policy and its implementation from time to time to monitor its continued effectiveness and we will disclose the implementation of our board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives, in our corporate governance report on an annual basis.

COMPLIANCE ADVISER

We have appointed Maxa Capital Limited as our compliance adviser pursuant to Rule 3A.19 and Rule 19A.05 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, our compliance adviser will advise our Company in the following circumstances:

- before the publication of any regulatory announcement, circular and financial report;
- where a transaction, which might be notifiable or connected transaction, is contemplated including shares issues and share repurchases;
- where our Company proposes to use the [**REDACTED**] from the [**REDACTED**] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of our Company regarding unusual movements in the price or trading volume of our Shares under Rule 13.10 of the Listing Rules.

The term of the appointment shall commence on the [**REDACTED**] and end on the date on which our Company distribute our annual report in respect of our financial results for the first full financial year commencing after the [**REDACTED**].

COMPENSATION OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Our Directors and members of our senior management receive compensation from our Group in the form of fees, salaries and other benefits and contribution to pension scheme.

The aggregate remuneration (including fees, salaries, allowances and benefits in kind, discretionary bonuses, retirement scheme contributions and equity-settled share-based payment) paid to our Directors and Supervisors for each of the two years ended December 31, 2021 and the six months ended June 30, 2022 was approximately RMB2.08 million, RMB19.53 million and RMB8.97 million, respectively. Save as disclosed above, no other amounts have been paid or are payable by any member of our Group to our Directors for each of the two years ended December 31, 2021.

The five highest paid individuals of the Group in respect of each of the two years ended December 31, 2021 and the six months ended June 30, 2022 included three employees who were not Directors. The aggregate amount of salaries, other benefits, discretionary bonuses and equity-settled share-based payment paid to such individuals (but excluding any of our Directors and chief executive) in respect of each of the two years ended December 31, 2021 and the six months ended June 30, 2022 was approximately RMB2.53 million, RMB10.60 million and RMB5.08 million, respectively.

No remuneration was paid by us to our Directors or the five highest paid individuals as an inducement to join or upon joining us or as a compensation for loss of office in respect of each of the two years ended December 31, 2021 and the six months ended June 30, 2022. Further, none of our Directors or Supervisors had waived or agreed to waive any remuneration during the same periods.

Under the arrangement currently in force, the aggregate remuneration (including fees, salaries, allowances and benefits in kind, discretionary bonuses, pension scheme contributions and equity-settled share-based payment) of our Directors and Supervisors for the year ending December 31, 2022 is estimated to be no more than approximately RMB6.67 million.

Our Board will review and determine the remuneration and compensation packages of our Directors and senior management and will, following the [**REDACTED**], receive recommendation from the remuneration and appraisal committee which will take into account salaries paid by comparable companies, time commitment and responsibilities of our Directors and performance of our Group.

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he/she did not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, either directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the Listing Rules.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader pharmaceutical and healthcare industries. However, as these non-executive Directors are neither our Controlling Shareholders nor members of our executive management team, we believe that their interests in such companies as directors would not render us incapable of carrying on our business independently from the other companies in which they may hold directorships from time to time.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts, confidentiality agreements and non-competition agreements with our senior management members and other key personnel. Below sets forth the key terms of these contracts we have entered into with our senior management and other key personnel.

Confidentiality

- Scope of confidential information. Information that the employee shall keep confidential includes but is not limited to trade secrets, inventions, discoveries, technical updates and improvements, data (including but not limited to clinical data), design, know-how, market and sales conditions, information of distributors, customers and employee compensation of our Group and the Luye Group.

- Confidential obligation. The employee shall keep confidential information in confidence and shall not use, divulge, publish or otherwise disclose or allow to be disclosed any aspect of confidential information to any entity or person whatsoever without the written consent of our Group.

- Confidential period. The confidentiality obligation shall continue to be in effect after the departure of the employee.

Non-competition

Within two years from the date of the employee's departure (the "**Non-compete Period**"), the employee shall not be engaged in any work, consulting or other services of any kind for any other person or business entity that competes with our Group. Our Group shall pay monthly compensation to the relevant employee during the Non-compete Period.

Service invention

The rights and interests in any invention, discovery, utility model, design and technical solution that produced by the employee within one year from the date of the employee's departure during their employment, including but not limited to those (i) related to the employee's work or (ii) developed in whole or in part using our equipment or confidential information, shall belong to us.

Non-solicitation

The employee agrees that he/she shall not directly or indirectly, (i) solicit, induce, recruit or encourage any of our employees to leave our Group; and (ii) solicit our clients, within two years after termination of employment with our Group.

CORPORATE GOVERNANCE

Our Company aims to achieve high standards of corporate governance which are crucial to the development and safeguard the interests of our Shareholders. To accomplish this, our Company expects to comply with the CG Code and the associated Listing Rules after the [**REDACTED**].

SHARE CAPITAL

As of the Latest Practicable Date, the share capital of our Company was RMB[498,583,294], divided into [498,583,294] Shares made up of [25,665,096] [**REDACTED**] foreign Shares and [472,918,198] Domestic Shares, with a nominal value of RMB1.00 each.

Assuming the [**REDACTED**] is not exercised, the share capital of our Company immediately after the completion of the [**REDACTED**] and conversion of Domestic Shares into H Shares will be as follows:

Number of Shares	Description of Shares	Approximate percentage of total share capital
[**REDACTED**]	H Shares to be converted from [**REDACTED**] foreign Shares[(Note)]	[**REDACTED**]
[**REDACTED**]	H Shares to be converted from Domestic Shares[(Note)]	[**REDACTED**]
[**REDACTED**]	H Shares to be issued under the [**REDACTED**]	[**REDACTED**]
[**REDACTED**]		100%

Note: Immediately prior to the conversion into H Shares, Shares held by Advantech Capital, Serendipity Investment, Starr International and Asian Alliance are [**REDACTED**] foreign Shares and the remaining Shares are Domestic Shares. Following conversion into H Shares, save for those Shares held by SIP Sungent, all of the Shares held by the Pre-[**REDACTED**] Investors, representing a total of approximately [**REDACTED**]% of the total issued share capital of our Company upon [**REDACTED**] (assuming the [**REDACTED**] is not exercised at all), will be counted towards the [**REDACTED**] for the purpose of Rule 8.08 of the Listing Rules.

Assuming the [**REDACTED**] is exercised in full, the share capital of our Company immediately after the completion of the [**REDACTED**] and conversion of Domestic Shares into H Shares will be as follows:

Number of Shares	Description of Shares	Approximate percentage of total share capital
[**REDACTED**]	H Shares to be converted from [**REDACTED**] foreign Shares[(Note)]	[**REDACTED**]
[**REDACTED**]	H Shares to be converted from Domestic Shares[(Note)]	[**REDACTED**]
[**REDACTED**]	H Shares to be issued under the [**REDACTED**]	[**REDACTED**]
[**REDACTED**]		100%

Note: Immediately prior to the conversion into H Shares, Shares held by Advantech Capital, Serendipity Investment, Starr International and Asian Alliance are [**REDACTED**] foreign Shares and the remaining Shares are Domestic Shares. Following conversion into H Shares, save for those Shares held by SIP Sungent, all of the Shares held by the Pre-[**REDACTED**] Investors, representing a total of approximately [**REDACTED**]% of the total issued share capital of our Company upon [**REDACTED**] (assuming the [**REDACTED**] is exercised in full), will be counted towards the [**REDACTED**] for the purpose of Rule 8.08 of the Listing Rules.

CONVERSION OF OUR DOMESTIC SHARES INTO H SHARES

If any of the Domestic Shares are to be converted, [**REDACTED**] and traded as H Shares on the Stock Exchange, such conversion, [**REDACTED**] and trading will need the approval of the relevant PRC regulatory authorities, including the CSRC, and the approval of the Stock Exchange.

[**REDACTED**]

[REDACTED]

INCREASE IN SHARE CAPITAL

As advised by our PRC Legal Adviser, pursuant to the Articles of Association and subject to the requirements of relevant PRC laws and regulations, our Company, upon the [**REDACTED**] of our H Shares, is eligible to enlarge its share capital by issuing either new H Shares or new Domestic Shares on the condition that such proposed issuance shall be approved by a special resolution of Shareholders in general meeting and by holders of Shares of that class of Shareholders whose interest is affected in a separate meeting conducted in accordance with the provisions of the Articles of Association and that such issuance complies with the Listing Rules and other relevant laws and regulations of Hong Kong. To adopt a special resolution of Shareholders in general meeting, more than the two thirds votes represented by the Shareholders (including proxies) present at the general meeting must be exercised in favor of the resolution. Resolutions of a class of Shareholders shall be passed by votes representing more than two thirds of Shareholders with voting rights attending the class Shareholders' meeting.

SHAREHOLDERS' APPROVAL FOR THE [REDACTED]

Approval from holders of the Shares is required for our Company to issue H Shares and seek the [**REDACTED**] of H Shares on the Stock Exchange. Our Company has obtained such approval at the Shareholders' general meeting held on February 11, 2022.

So far as is known to our Directors, as of the Latest Practicable Date and immediately prior to and following the completion of the [**REDACTED**] (without taking into account of any Shares which may be issued pursuant to the exercise of the [**REDACTED**]), the following persons had or will have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of any member of our Group:

		Shares held as of the Latest Practicable Date and immediately prior to the [REDACTED][(1)]			Shares held immediately following the completion of the [REDACTED][(1)]		
Name of Shareholder	Nature of interest	Class of Shares	Number of Shares	Approximate percentage of shareholding in the total issued share capital	Class of Shares	Number of Shares	Approximate percentage of shareholding in the total issued share capital
Shandong Luye	Beneficial owner[(2)]	Domestic Shares	[360,596,456] (L)	[72.32]%	H Shares	[REDACTED] (L)	[REDACTED]%
Yantai Luye	Interest in a controlled corporation[(2)]	Domestic Shares	[360,596,456] (L)	[72.32]%	H Shares	[REDACTED] (L)	[REDACTED]%
Luye HK	Interest in a controlled corporation[(2)]	Domestic Shares	[360,596,456] (L)	[72.32]%	H Shares	[REDACTED] (L)	[REDACTED]%
AsiaPharm	Interest in a controlled corporation[(2)]	Domestic Shares	[360,596,456] (L)	[72.32]%	H Shares	[REDACTED](L)	[REDACTED]%
Luye Pharma	Interest in a controlled corporation[(2)]	Domestic Shares	[360,596,456] (L)	[72.32]%	H Shares	[REDACTED] (L)	[REDACTED]%

Notes:

(1) The letter "L" denotes the person's long position in our Shares.

(2) Shandong Luye is wholly owned by Yantai Luye, which in turn is wholly owned by Luye HK. Luye HK is in turn wholly owned by AsiaPharm and AsiaPharm is wholly owned by Luye Pharma. Accordingly, each of Luye Pharma, AsiaPharm, Luye HK and Yantai Luye is deemed under the SFO to be interested in the Shares held by Shandong Luye.

Except as disclosed above, our Directors are not aware of any other person who will, immediately following the completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised), have any interest and/or short positions in the Shares of our Company which would fall to be disclosed to us pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or, who are, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

You should read the following discussion in conjunction with the consolidated financial statements and the notes thereto included in the Accountants' Report in Appendix I to this document which has been prepared in accordance with IFRS, and the selected historical financial information and operating data included elsewhere in this document.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future development, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the sections headed "Risk Factors" and "Forward-Looking Statements" and elsewhere in this document.

OVERVIEW

We are an integrated biopharmaceutical company committed to developing, manufacturing and commercializing high quality biologics in China and overseas. Since our inception in 2013, we have fostered multiple key elements we believe will help us capture the strong market opportunity in biologics, including:

- a management team with extensive industry experience and market insight that has pushed forward our strategic plans including successfully bringing Boyounuo® (BA1101) to market in China in May 2021;
- a robust and risk-balanced portfolio, which brings us clear short-term commercial visibility and allows us to pursue long-term sustainable growth;
- an integrated biopharmaceutical platform; and
- collaboration with various resourceful business partners, laying the foundation for our strong commercialization capability.

We focus our platform, people and partnerships on offering access to innovative biologics as well as affordable biosimilars. During the Track Record Period, we recorded a revenue of nil in 2020 and RMB158.7 million in 2021 and RMB12.1 million and RMB220.7 million for the six months ended June 30, 2021 and 2022, respectively, which reflects our sales of Boyounuo® (BA1101) since its launch in May 2021. We recorded gross profit of nil and RMB106.5 million for the years ended December 31, 2020 and 2021, respectively, and RMB8.8 million and RMB147.3 million for the six months ended June 30, 2021 and 2022, respectively. We recorded net loss of RMB240.5 million and RMB225.4 million for the years ended December 31, 2020 and 2021, respectively, and RMB127.9 million and RMB153.3 million for the six months ended June 30, 2021 and 2022, respectively.

We expect to incur an increased amount of operating expenses in the near term as we further our pre-clinical research, continue the clinical development of, and seek regulatory approval for, our product candidates, launch our pipeline products, and expand the commercialization of our approved products in China and overseas. We expect that our financial performance will fluctuate from period to period due to the development status of our product candidates, regulatory approval timeline and commercialization of our product candidates after approval.

BASIS OF PREPARATION

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("**IFRS**"), which comprise all standards and interpretations approved by the International Accounting Standards Board (the "**IASB**").

The consolidated financial information has been prepared under the historical cost convention, except for notes receivable which has been measured at fair value. The consolidated financial information is presented in RMB and all values are rounded to the nearest thousand except when otherwise indicated. We have early adopted all IFRSs effective for the Track Record Period together with relevant transitional provisions in the preparation of the historical financial information throughout the Track Record Period.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Our results of operations and financial condition have been, and are expected to continue to be, affected by a variety of factors, including those set forth below:

General factors

Our business and operating results are affected by general factors affecting the global and China biologics market, which include:

- relevant laws and regulations, governmental policies and initiatives affecting the global and China biologics market;
- growth and competition environment of the global and China biologics market; and
- political, economic and social instability of different local markets.

Company specific factors

While our business is influenced by general factors affecting the global and China biologics market, our results of operations are also affected by company specific factors, including the following:

Our ability to successfully commercialize our drug candidates

Our business and results of operations depend on our ability to successfully commercialize our drug candidates. We launched Boyounuo® (BA1101) in May 2021 in China and recorded a revenue of RMB158.7 million from its sales for the year ended December 31, 2021, and RMB220.7 million from its sales for the six months ended June 30, 2022. As of the Latest Practicable Date, we had a total of 13 drug candidates. In particular, we had 11 drug candidates which had entered or completed clinical trials or received the IND approvals from the CDE, comprising one drug candidate with BLA approved, two in Phase 3 clinical trial,one in Phase 2 clinical trial, four in Phase 1 clinical trial, and two received the IND approvals from the CDE in China. Two of these drug candidates, namely BA1102 and BA6101, were also in Phase 1 clinical trial in the EU. Accordingly, during the Track Record Period our revenue consisted solely of the sales of Boyounuo® (BA1101) and our revenue may continue to rely on its sales performance and the progress of the future commercialization of our drug candidates which are in different development stages. See "Risk Factors — Risks relating to the development, clinical trials and regulatory approval of our drug candidates" and "Risk Factors — Risks relating to the commercialization of our drug candidates" for further details of various risks and uncertainties in connection with our commercialization efforts and plans.

Cost structure

During the Track Record Period our results of operations were significantly affected by our cost structure, which primarily consists of research and development costs, administrative expenses, and selling and distribution expenses.

Research and development activities are central to our business model. For the years ended December 31, 2020 and 2021, our research and development costs amounted to RMB236.3 million and RMB231.6 million, respectively, and for the six months ended June 30, 2021 and 2022, they amounted to RMB111.6 million and RMB169.1 million, respectively. Research and development costs primarily consist of:

- R&D service fees mainly paid to CROs and hospitals for technological services provided in relation to certain pre-clinical studies and clinical trials,
- staff costs of and expenses related to the employee stock ownership plan (the "**ESOP**") for our R&D personnel,
- expenses of raw materials and consumables used in pre-clinical studies and clinical trials,

- depreciation and amortization expenses, and

- others mainly including translation fee for filing purpose, utilities, travel expenses, IP registration fees, maintenance fee and rent expenses.

Our current research and development activities mainly relate to the clinical advancement of our product candidates in our pipeline. We expect our research and development costs to continue to increase for the foreseeable future, as we move more drug candidates into clinical trials, and as we continue to support the clinical trials of our drug candidates as treatments for additional indications. See "— Description of major line items in our consolidated statement of profit or loss — Research and development costs" in this section for further details. We intend to continue to advance the development of our drug candidates, and the research and development costs are therefore expected to continue to be a major component of our operating expenses.

For the years ended December 31, 2020 and 2021, our administrative expenses amounted to RMB4.5 million and RMB42.2 million, respectively, and for the six months ended June 30, 2021 and 2022, they amounted to RMB18.2 million and RMB37.6 million, respectively, which consist primarily of (i) staff costs of and expenses related to the ESOP for our administrative personnel, (ii) professional service fees mainly representing auditors fees and consulting fees, (iii) [**REDACTED**] expenses for the proposed [**REDACTED**], (iv) travel and business development expenses, (v) utilities and office expenses and (vi) others. We also expect our administrative expenses to continue to increase in the foreseeable future to support our expanding business operation. These cost increases will likely be due to increased headcount, increased employee salaries and benefits, and expanded infrastructure. We also anticipate increased legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong. See "— Description of major line items in our consolidated statement of profit or loss — Administrative expenses" in this section for further details.

In addition to the research and development costs and administrative expenses, we also anticipate that our selling and distribution expenses will increase as we continue to expand sales of Boyounuo® (BA1101) and prepare for the commercialization of our drug candidates. For the years ended December 31, 2020 and 2021, our selling and distribution expenses amounted to nil and RMB54.0 million, respectively, and for the six months ended June 30, 2021 and 2022, they amounted to RMB5.9 million and RMB100.8 million, respectively, which consisted primarily of (i) promotion expenses mainly in connection with product promotion services provided by independent third-party promoters, (ii) staff costs of our in-house sales and marketing personnel and (iii) others mainly including conference fees and travel expenses and were mostly related to the selling and distribution of Boyounuo® (BA1101) launched in May 2021. See "— Description of major line items in our consolidated statement of profit or loss — Selling and distribution expenses" in this section for further details.

Government healthcare spending, medical reimbursement and drug pricing policies

We expect that the future sales performance of our drug and drug candidates will depend in part on the level of government spending on healthcare and the coverage of our drug and drug candidates under government medical reimbursement schemes. For example, we expect the PRC to be a major market for our drug and drug candidates. In line with the overall growth in healthcare service industry and increasing healthcare investment in China, the PRC government in the last several years has enacted various policies and official plans aimed at encouraging healthcare infrastructure development and improving accessibility to healthcare services. In particular, growth in population coverage and funding for public medical insurance programs have significantly improved patients' ability to pay for medical treatment, resulting in considerable growth in both patient enrollment and average spending.

At the same time, PRC regulations and medical insurance plans also exert significant influence over drug pricing, such as, by imposing reimbursement caps, which could affect patients' access to our drugs as well as our profitability. The inclusion of our drug candidates in the NRDL and being eligible for local medical insurance coverage upon commercialization may significantly increase the demand for such products. As more biologics are included in the NRDL and become eligible for local medical insurance coverage, biologics are expected to become more affordable, which will allow greater market access. This, in turn, may have a positive impact on the availability and sales volume of our drugs and a negative impact on our pricing and profitability.

In addition, in China, each public medical institution has historically procured drugs through a provincial centralized drug purchase platform, and made substantially all of its purchases of pharmaceutical products through a centralized tender process. We plan to participate in such tender when opportunity arises and if we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public hospitals and other medical institutions at the bid prices, which is the primary determinant of the prices at which we sell the relevant products to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. See "Risk Factors — Risks relating to the commercialization of our drug candidates — We have only recently begun commercializing our drug products and have just started to generate revenue from product sales, and we cannot assure you that we will be able to generate substantial revenue in the future" for further details.

We may encounter similar government insurance schemes in other jurisdictions where we seek to commercialize our drug candidates, and how our drug candidates are reimbursed under such schemes may facilitate or hinder their market acceptance and commercial success in those jurisdictions, as well. See "Risk Factors — Risks relating to the commercialization of our drug candidates — Even if we are able to commercialize any drug candidates, the drugs may become subject to national or other third-party reimbursement practices, healthcare reform initiatives or unfavorable pricing regulations, which could harm our business" for further details.

Funding for our operations

During the Track Record Period, we funded our operations primarily through equity and debt financing and partly through the sales of Boyounuo® (BA1101). With the continuing expansion of our business and development of drug candidates, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations will affect our cash flow and results of operation. See "— Indebtedness" in this section and "Risk Factors — Risks relating to our financial prospects and need for additional capital — We had substantial indebtedness and net current liabilities at certain points during the Track Record Period, and may continue to incur significant debt going forward" for further details.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

This discussion and analysis of our financial position and results of operations is based on our consolidated financial statements, which have been prepared in accordance with IFRS. The preparation of our consolidated financial statements requires management to make estimates, judgments and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities at the end of each period of the Track Record Period. Uncertainty about these estimates and assumptions could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods. Our more critical accounting policies and significant estimates, assumptions and judgments are described below. See notes 2 and 3 to the Accountants' Report in Appendix I to this document for further details on our accounting policies, estimates and judgments.

Critical accounting policies

Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

The expenditures on an internal research and development project are classified into expenditures in the research phase and expenditures in the development phase based on their nature and whether there is material uncertainty that the research and development activities can form an intangible asset at end of the project.

Expenditure in the development phase is capitalized and deferred if, and only if, all of the following have been demonstrated: (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale; (ii) the intention to complete the intangible asset and use or sell it; (iii) the ability to use or sell the intangible asset; (iv) how the intangible asset will generate probable future economic benefits; (v) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and (vi) its ability to measure reliably the expenditure attributable to the intangible asset during its development. Product development expenditure which does not meet these criteria is expensed when incurred.

The specific criteria for the capitalization of development costs are as follows:

As for biosimilar products, expenditures incurred after the commencement of Phase III clinical trial for the medicines are capitalized and recognized as assets when the above six criteria are met.

As for innovative products, expenditures incurred after obtaining the new drug application approval from the drug regulatory organization are capitalized and recognized as assets when the above six criteria are met.

Deferred development costs are stated at cost less any impairment losses and are amortized using the straight-line basis over the commercial lives of the underlying products not exceeding twenty years, commencing from the date when the regulatory and marketing approval is received, which is determined by considering the estimates of useful lives of similar products and the market condition. See note 2.3 to the Accountants' Report in Appendix I to this document for further details on the accounting policy of intangible assets.

Impairment of financial assets

We recognize an allowance for expected credit losses ("**ECLs**") for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that we expect to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms. See note 2.3 to the Accountants' Report in Appendix I to this document for further details of the accounting policy of impairment of financial assets.

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined on the weighted average basis and, in the case of work in progress and finished goods, comprises direct materials, direct labor and an appropriate proportion of overheads. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Revenue recognition

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which our Group expects to be entitled in exchange for those goods or services.

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset. See note 2.3 to the Accountants' Report in Appendix I to this document for further details of the accounting policy of revenue recognition.

Contract liabilities

A contract liability is recognized when a payment is received or a payment is due (whichever is earlier) from a customer before we transfer the related goods or services. Contract liabilities are recognized as revenue when we perform under the contract (i.e., transfers control of the related goods or services to the customer).

Critical accounting judgments and estimates

Research and development costs

All research costs are charged to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred in accordance with the accounting policy for research and development costs. Determining the amounts to be capitalized requires our management to make assumptions and judgments regarding to technical feasibility of completing the intangible asset, future economic benefits and so forth.

Lease term of contracts with renewal options

We have several lease contracts that include extension and termination options. We apply judgement in evaluating whether or not to exercise the option to renew or terminate the lease. We consider all relevant factors that create an economic incentive for us to exercise either the renewal or termination option. After the commencement date, we reassess the lease term to determine if there is a significant event or change in circumstances that is within our control and affects our ability to exercise or not to exercise the option to renew or to terminate the lease (e.g., construction of significant leasehold improvements or significant customisation to the leased asset).

We include the renewal period as part of the lease term for leases of laboratory and machinery and equipment due to the significance of these assets to its operations. These leases have a short non-cancellable period (i.e., one and a half to five years) and there will be a significant negative effect on production if a replacement is not readily available.

Incremental borrowing rate

We cannot readily determine the interest rate implicit in a lease, and therefore, we use an incremental borrowing rate ("**IBR**") to measure lease liabilities. The IBR is the rate of interest that we would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what we "would have to pay", which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary's functional currency). We estimate the IBR using observable inputs (such as market interest rates) when available and are required to make certain entity-specific estimates (such as the subsidiary's stand-alone credit rating).

Impairment of non-financial assets

We assess whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Track Record Period. Indefinite life intangible assets are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, our management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Deferred tax assets

Deferred tax assets are recognized for unused tax losses and deductible temporary differences to the extent that it is probable that taxable profits will be available against which the losses and temporary differences can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies.

Fair value measurement of share-based payments

We have a share-based payment plan and granted equity interests to our Company's directors and our employees. The fair value of the granted equity interests is determined by the back-solve method and equity value allocation based on the option pricing model at the grant date. Significant estimates on assumptions, including expected volatility and risk-free interest rate, are made by the board of directors of our Company.

DESCRIPTION OF MAJOR LINE ITEMS IN OUR CONSOLIDATED STATEMENT OF PROFIT OR LOSS

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2020	2021	2021	2022
	(RMB in thousands)		(unaudited)	
REVENUE	–	158,704	12,094	220,690
Cost of sales	–	(52,190)	(3,311)	(73,421)
Gross profit	–	106,514	8,783	147,269
Other income and gains	12,073	13,365	5,745	13,508
Research and development costs	(236,317)	(231,567)	(111,558)	(169,057)
Administrative expenses	(4,464)	(42,165)	(18,220)	(37,563)
Selling and distribution expenses	–	(54,048)	(5,874)	(100,827)
Other expenses	(11)	(5,917)	(1,228)	(3)
Finance costs	(11,819)	(11,599)	(5,575)	(6,622)
LOSS BEFORE TAX	(240,538)	(225,417)	(127,927)	(153,295)
Income tax expense	–	–	–	–
LOSS FOR THE YEAR/PERIOD	(240,538)	(225,417)	(127,927)	(153,295)
Attributable to:				
Owners of the parent	(240,538)	(225,417)	(127,927)	(153,295)
OTHER COMPREHENSIVE LOSS				
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	–	(128)	14	1,077
OTHER COMPREHENSIVE LOSS FOR THE YEAR/PERIOD, NET OF TAX	–	(128)	14	1,077
TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD	(240,538)	(225,545)	(127,913)	(152,218)
Attributable to:				
Owners of the parent	(240,538)	(225,545)	(127,913)	(152,218)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT				
Basic and diluted (RMB)	(6.13)	(0.47)	(0.28)	(0.31)

Revenue

During the Track Record Period, we derived revenue solely from the sales of Boyounuo® (BA1101) in China to our distributors since its launch in May 2021. Our revenue was nil and RMB158.7 million for the years ended December 31, 2020 and 2021, respectively, and RMB12.1 million and RMB220.7 million for the six months ended June 30, 2021 and 2022, respectively.

Cost of sales

During the Track Record Period, our cost of sales primarily represents (i) raw materials and consumables used for or scrapped in the course of the production of our products, (ii) depreciation and amortization expenses of production equipment and facilities and intangible assets associated with our production, (iii) labor costs associated with our production and (iv) others mainly including utilities and maintenance fee. Our cost of sales was nil and RMB52.2 million for the years ended December 31, 2020 and 2021, respectively, and RMB3.3 million and RMB73.4 million for the six months ended June 30, 2021 and 2022, respectively. The following table sets forth a breakdown of our cost of sales for the periods indicated:

	Year ended December 31,				Six months ended June 30,			
	2020		2021		2021		2022	
	RMB	*%*	*RMB*	*%*	*RMB*	*%*	*RMB*	*%*
	(RMB in thousands, except percentages)				(unaudited)			
Raw materials and consumables	–	–	20,797	39.8	969	29.3	29,249	39.8
Depreciation and amortization expenses	–	–	13,616	26.1	396	12.0	21,713	29.6
Labor costs	–	–	11,422	21.9	1,574	47.5	11,739	16.0
Others	–	–	6,355	12.2	372	11.2	10,720	14.6
Total	**–**	**–**	**52,190**	**100.0**	**3,311**	**100.0**	**73,421**	**100.0**

Gross profit

As a result of the foregoing, our gross profit was nil and RMB106.5 million for the years ended December 31, 2020 and 2021, respectively, and RMB8.8 million and RMB147.3 million for the six months ended June 30, 2021 and 2022, respectively.

Other income and gains

During the Track Record Period, our other income and gains primarily consist of government grants representing subsidies received from local government authorities primarily to support our research and development activities and operation, bank interest income, foreign exchange gain, net, interest income from a related party, LIG, and others. Our other income and gains were RMB12.1 million and RMB13.4 million for the years ended December 31, 2020 and 2021, respectively, and RMB5.7 million and RMB13.5 million for the six months ended June 30, 2021 and 2022, respectively. The following table sets forth a breakdown of our other income and gains for the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2020	2021	2021	2022
	(RMB in thousands)		(unaudited)	
Government grants	10,878	4,264	1,327	6,903
Bank interest income	31	9,101	4,418	3,889
Foreign exchange gain, net	–	–	–	2,636
Interest income from a related party	1,164	–	–	–
Others	–	–	–	80
Total	**12,073**	**13,365**	**5,745**	**13,508**

We recognize government grants as other income and gains upon the receipt of government grants which is to compensate research and development costs we incurred or upon the fulfilment of the requirements and conditions attached to such government grants. To the extent any requirement or condition attached to such government grants has not been met, we record such portion of government grants under liabilities. See "— Description of major line items in our consolidated statements of financial position — Government grants" in this section for further details.

Research and development costs

During the Track Record Period, our research and development costs primarily consist of (i) R&D service fees mainly paid to CROs and hospitals for technological services provided in relation to certain pre-clinical studies and clinical trials, (ii) expenses of raw materials and consumables used in pre-clinical studies and clinical trials, (iii) staff costs and expenses related to the ESOP for our R&D personnel, (iv) depreciation and amortization expenses mainly including depreciation expenses for property, plant and equipment as well as amortization expenses for intangible assets and right-of-use assets and (v) others mainly including translation fee for filing purpose, utilities, travel expenses, IP registration fees, maintenance fee and rent expenses. Our research and development costs were RMB236.3 million and RMB231.6 million for the years ended December 31, 2020 and 2021, respectively, and RMB111.6 million and RMB169.1 million for the six months ended June 30, 2021 and 2022, respectively. For the years ended December 31, 2020 and 2021 and for the six months ended June 30, 2021 and 2022, the research and development costs for the Core Products were RMB97.3 million, RMB50.8 million, RMB26.4 million and RMB21.3 million, respectively, representing 41.2%, 21.9%, 23.6% and 12.6% of our total research and development costs for the same period, respectively. The following table sets forth a breakdown of our research and development costs for the periods indicated:

	Year ended December 31,				Six months ended June 30,			
	2020		2021		2021		2022	
	RMB	*%*	*RMB*	*%*	*RMB*	*%*	*RMB*	*%*
	(RMB in thousands, except percentages)				(unaudited)			
R&D service fees								
– pre-clinical studies	54,648	23.1	44,469	19.2	27,029	24.2	45,583	27.0
– clinical trials	24,235	10.3	38,238	16.5	19,055	17.1	23,253	13.8
Raw materials and consumables expenses	92,717	39.2	54,459	23.5	24,361	21.8	41,093	24.3
Staff costs and ESOP	26,379	11.2	59,164	25.5	24,359	21.8	35,982	21.3
Depreciation and amortization expenses	15,882	6.7	23,376	10.1	10,939	9.8	13,521	8.0
Others	22,456	9.5	11,861	5.1	5,815	5.2	9,625	5.7
Total	**236,317**	**100.0**	**231,567**	**100.0**	**111,558**	**100.0**	**169,057**	**100.0**

Administrative expenses

During the Track Record Period, our administrative expenses primarily consist of (i) **[REDACTED]** expenses for the proposed **[REDACTED]**, (ii) staff costs and expenses related to the ESOP for our administrative personnel, (iii) utilities and office expenses, (iv) travel and business development expenses, (v) professional service fees mainly representing consulting fees and auditors fees and (vi) others mainly including (a) property tax, stamp duty, and other levies for education and city development and (b) recruiting costs. Our administrative expenses were RMB4.5 million and RMB42.2 million for the years ended December 31, 2020 and 2021, respectively, and RMB18.2 million and RMB37.6 million for the six months ended June 30, 2021 and 2022, respectively. The following table sets forth, a breakdown of our administrative expenses for the periods indicated:

	Year ended December 31,				Six months ended June 30,			
	2020		2021		2021		2022	
	RMB	*%*	*RMB*	*%*	*RMB*	*%*	*RMB*	*%*
	(RMB in thousands, except percentages)				(unaudited)			
[REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Staff costs and ESOP	1,978	44.3	28,863	68.5	11,850	65.0	13,302	35.4
Utilities and office expenses	345	7.7	1,253	3.0	860	4.7	1,223	3.3
Travel and business development expenses	291	6.5	1,808	4.3	568	3.1	689	1.8
Professional service fees	1,270	28.4	2,506	5.9	1,768	9.7	346	0.9
Others	580	13.0	5,364	12.7	2,403	13.3	2,834	7.6
Total	**4,464**	**100.0**	**42,165**	**100.0**	**18,220**	**100.0**	**37,563**	**100.0**

Selling and distribution expenses

During the Track Record Period, our selling and distribution expenses were mainly attributable to the sales of Boyounuo® (BA1101) that commenced in May 2021 and primarily consist of (i) promotion expenses mainly in connection with product promotion services provided by independent third-party promoters, (ii) staff costs of our in-house sales and marketing personnel and (iii) others mainly including conference fees and travel expenses. Our selling and distribution expenses were nil and RMB54.0 million for the years ended December 31, 2020 and 2021, respectively, and RMB5.9 million and RMB100.8 million for the six months ended June 30, 2021 and 2022, respectively. The significant increase in promotion expenses during the Track Record Period was mainly in line with the growth of the revenue generated from the sales of Boyounuo® (BA1101) that commenced in May 2021. The following table sets forth a breakdown of our selling and distribution expenses for the periods indicated:

	Year ended December 31,				Six months ended June 30,			
	2020		2021		2021		2022	
	RMB	*%*	*RMB*	*%*	*RMB*	*%*	*RMB*	*%*
	(RMB in thousands, except percentages)				(unaudited)			
Promotion expenses	–	–	46,564	86.1	3,752	63.9	93,922	93.2
Staff costs	–	–	4,029	7.5	1,623	27.6	6,162	6.1
Others	–	–	3,455	6.4	499	8.5	743	0.7
Total	**–**	**–**	**54,048**	**100.0**	**5,874**	**100.0**	**100,827**	**100.0**

Other expenses

Our other expenses represent foreign exchange loss mainly as a result of the depreciation of U.S. dollars we received through pre-[**REDACTED**] investments in 2021 as well as the loss on disposal of items of property, plant and equipment. Our other expenses were RMB11,000 and RMB5.9 million for the years ended December 31, 2020 and 2021, respectively, and RMB1.2 million and RMB3,000 for the six months ended June 30, 2021 and 2022, respectively. The following table sets forth a breakdown of our other expenses for the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2020	**2021**	**2021**	**2022**
		(RMB in thousands)		
			(unaudited)	
Foreign exchange loss	–	5,851	1,163	–
Loss on disposal of items of property, plant and equipment	11	66	65	3
Total	**11**	**5,917**	**1,228**	**3**

Finance costs

Our finance costs primarily represent the interest expenses incurred on our (i) loans and borrowings, (ii) lease liabilities of our leased properties and (iii) others representing our discounted notes receivable. Our finance costs were RMB11.8 million and RMB11.6 million for the years ended December 31, 2020 and 2021, respectively, and RMB5.6 million and RMB6.6 million for the six months ended June 30, 2021 and 2022, respectively. See "— Indebtedness" in this section for further details. The following table sets forth a breakdown of our finance costs for the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2020	**2021**	**2021**	**2022**
		(RMB in thousands)		
			(unaudited)	
Interest on bank loans	11,222	10,895	5,189	5,897
Interest on lease liabilities	597	704	386	264
Others	–	–	–	461
Total	**11,819**	**11,599**	**5,575**	**6,622**

Income tax expense

We are subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which our member companies are domiciled and operate. During the Track Record Period, we were generally taxed at the prevailing statutory corporate income tax rate of 25% on the taxable income in China, 21% on the taxable income arising in the United States and 17% on the taxable income in Singapore. As we were loss-making during the Track Record Period, we did not incur income tax expenses on profits.

PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Six months ended June 30, 2022 compared to six months ended June 30, 2021

Revenue

Our revenue increased significantly from RMB12.1 million for the six months ended June 30, 2021 to RMB220.7 million for the six months ended June 30, 2022, mainly because we commenced the sales of Boyounuo® (BA1101) in May 2021 from which the sales continued till the end of the first half of 2021 compared to the sales we had in the entire six months period in the first half of 2022. The sales of Boyounuo® (BA1101) for the six months ended June 30, 2022 was also affected by the patients' limited access to medical services in the affected regions due to COVID-19 during that period.

Cost of sales

Our cost of sales increased significantly from RMB3.3 million for the six months ended June 30, 2021 to RMB73.4 million for the six months ended June 30, 2022, mainly because we had increased production volume of Boyounuo® (BA1101) in the first half of 2022 primarily driven by its increased sales and the longer sales period in the first half of 2022, compared to the shorter sales period from May 2021 when we commenced the sales of Boyounuo® (BA1101) till the end of the first half of 2021.

Gross profit

As a result of the foregoing, our gross profit increased from RMB8.8 million for the six months ended June 30, 2021 to RMB147.3 million for the six months ended June 30, 2022.

Other income and gains

Our other income and gains increased significantly from RMB5.7 million for the six months ended June 30, 2021 to RMB13.5 million for the six months ended June 30, 2022, primarily due to the increases in (i) government grants from RMB1.3 million for the six months ended June 30, 2021 to RMB6.9 million for the six months ended June 30, 2022 mainly because we received government subsidies of RMB4.5 million to support our research and development activities, and we also recognized another government grant of RMB1.8 million related to our research on COVID-19 after the conditions to the grant were satisfied and (ii) foreign exchange gain, net from nil for the six months ended June 30, 2021 to RMB2.6 million for the six months ended June 30, 2022, mainly attributable to the appreciation of U.S. dollars we received through pre-[**REDACTED**] investments.

Research and development costs

Our research and development costs increased by 51.5% from RMB111.6 million for the six months ended June 30, 2021 to RMB169.1 million for the six months ended June 30, 2022, primarily due to the increases in (i) R&D service fees from RMB46.1 million for the six months ended June 30, 2021 to RMB68.8 million for the six months ended June 30, 2022 mainly in relation to research projects, specifically BA1301 of which the research and development commenced in May 2021, (ii) raw materials and consumables expenses from RMB24.4 million for the six months ended June 30, 2021 to RMB41.1 million for the six months ended June 30, 2022 mainly due to the increased raw materials and consumables used for our research projects, specifically the research and development of BA5101 which entered its Phase 1 clinical trial stage and BA1301 which showed steady progress, and (iii) staff costs and expenses related to the ESOP for our R&D personnel from RMB24.4 million for the six months ended June 30, 2021 to RMB36.0 million for the six months ended June 30, 2022 mainly as a result of (a) the increase in the number of R&D personnel and (b) our equity interests granted to eligible R&D employees being apportioned during the six months in the first half of 2022 which is longer than about five months in the corresponding period of the previous year while the equity interest was first granted to the relevant employees on January 27, 2021.

Administrative expenses

Our administrative expenses increased significantly from RMB18.2 million for the six months ended June 30, 2021 to RMB37.6 million for the six months ended June 30, 2022, primarily due to the increase in the [**REDACTED**] expenses from RMB[**REDACTED**] for the six months ended June 30, 2021 to RMB[**REDACTED**] for the six months ended June 30, 2022 as the proposed [**REDACTED**] progressed.

Selling and distribution expenses

Our selling and distribution expenses increased significantly from RMB5.9 million for the six months ended June 30, 2021 to RMB100.8 million for the six months ended June 30, 2022, mainly attributable to the increase in the promotion expenses from RMB3.8 million for the six months ended June 30, 2021 to RMB93.9 million for the six months ended June 30, 2022 mainly incurred for independent third-party promotors attributable to the sales of Boyounuo® (BA1101), which was generally in line with the revenue growth during the same period.

Other expenses

Our other expenses decreased significantly from RMB1.2 million for the six months ended June 30, 2021 to RMB3,000 for the six months ended June 30, 2022, primarily due to the decrease in foreign exchange loss from RMB1.2 million for the six months ended June 30, 2021 to nil for the six months ended June 30, 2022 mainly as a result of the appreciation of U.S. dollars we received through pre-[**REDACTED**] investments.

Finance costs

Our finance costs increased by 18.8% from RMB5.6 million for the six months ended June 30, 2021 to RMB6.6 million for the six months ended June 30, 2022, primarily due to the increases in (i) interest on bank loans from RMB5.2 million for the six months ended June 30, 2021 to RMB5.9 million for the six months ended June 30, 2022 because we obtained the Bank of China Loan in late January 2021 thus incurring more interest expenses in the first half of 2022 and (ii) interest on discounted notes receivable from nil for the six months ended June 30, 2021 to RMB0.5 million for the six months ended June 30, 2022.

Loss before tax

As a result of the foregoing, our loss before tax increased by 19.8% from RMB127.9 million for the six months ended June 30, 2021 to RMB153.3 million for the six months ended June 30, 2022.

Income tax expense

As we were loss-making for the six months ended June 30, 2021 and 2022, we did not incur income tax expenses.

Loss for the period

As a result of the foregoing, our loss for the period increased by 19.8% from RMB127.9 million for the six months ended June 30, 2021 to RMB153.3 million for the six months ended June 30, 2022.

Year ended December 31, 2021 compared to year ended December 31, 2020

Revenue

Our revenue increased from nil for the year ended December 31, 2020 to RMB158.7 million for the year ended December 31, 2021, solely attributable to the sales of Boyounuo® (BA1101) that commenced in May 2021. Our in-house sales and marketing team, together with our third-party promoters, including AstraZeneca China, contributed to the fast expansion of our market and the significant enhancement of product publicity and market acceptance since the product debut in May 2021.

Cost of sales

Our cost of sales increased from nil for the year ended December 31, 2020 to RMB52.2 million for the year ended December 31, 2021, solely attributable to the sales of Boyounuo® (BA1101) mainly reflecting (i) raw materials and consumables used for or scrapped in the course of the production of our products, (ii) depreciation and amortization expenses, (iii) labor costs and (iv) others mainly including utilities and maintenance fee.

Gross profit

As a result of the foregoing, our gross profit increased from nil for the year ended December 31, 2020 to RMB106.5 million for the year ended December 31, 2021.

Other income and gains

Our other income and gains increased by 10.7% from RMB12.1 million for the year ended December 31, 2020 to RMB13.4 million for the year ended December 31, 2021, primarily due to the increase in bank interest income from RMB31,000 for the year ended December 31, 2020 to RMB9.1 million for the year ended December 31, 2021, mainly attributable to the proceeds we received through pre-[**REDACTED**] investments, partially offset by the decrease in government grants mainly due to different grants we received each year.

Research and development costs

Our research and development costs decreased by 2.0% from RMB236.3 million for the year ended December 31, 2020 to RMB231.6 million for the year ended December 31, 2021, primarily due to the decreases in (i) raw materials and consumables expenses from RMB92.7 million for the year ended December 31, 2020 to RMB54.5 million for the year ended December 31, 2021 mainly due to the capitalization of certain expenses related to BA1102 and BA9101 as deferred development cost in 2021 after meeting the criteria for capitalization and (ii) others from RMB22.5 million for the year ended December 31, 2020 to RMB11.9 million for the year ended December 31, 2021 mainly due to (a) the termination of leases of certain premises after our acquisition of such premises from Shandong Luye through capital injection via property, (b) the reduced utilities used for the manufacturing of LY-CovMab samples used in its clinical trials based on our needs and (c) the reduced translation fee for filing purpose.

The deceases were partially offset by a significant increase in (i) staff costs and expenses related to the ESOP for our R&D personnel from RMB26.4 million for the year ended December 31, 2020 to RMB59.2 million for the year ended December 31, 2021 mainly as a result of increases in the number of R&D personnel as well as our equity interests granted to eligible R&D employees in 2021 and (ii) depreciation and amortization expenses from RMB15.9 million for the year ended December 31, 2020 to RMB23.4 million for the year ended December 31, 2021 related to our plants, equipment and newly leased premises and equipment in Boston in 2021.

Administrative expenses

Our administrative expenses increased significantly from RMB4.5 million for the year ended December 31, 2020 to RMB42.2 million for the year ended December 31, 2021, primarily due to the increases in (i) staff costs and expenses related to the ESOP for our administrative personnel from RMB2.0 million for the year ended December 31, 2020 to RMB28.9 million for the year ended December 31, 2021 mainly as a result of increases inthe number of administrative personnel as well as our equity interests granted to eligible administrative employees in 2021, (ii) others from RMB0.6 million for the year ended December 31, 2020 to RMB5.4 million for the year ended December 31, 2021 mainly reflecting the increases in property tax, stamp duty and recruiting costs, which were in line with our expanded business and (iii) [**REDACTED**] expenses of RMB[**REDACTED**] incurred in 2021 for the proposed [**REDACTED**].

Selling and distribution expenses

Our selling and distribution expenses increased from nil for the year ended December 31, 2020 to RMB54.0 million for the year ended December 31, 2021, mainly attributable to the sales of Boyounuo® (BA1101), in particular, (i) the promotion expenses of RMB46.6 million mainly paid to independent third-party promoters, (ii) the staff costs of our in-house sales and marketing personnel of RMB4.0 million and (iii) others mainly including conference fees and travel expenses of RMB3.5 million.

Other expenses

Our other expenses increased significantly from RMB11,000 for the year ended December 31, 2020 to RMB5.9 million for the year ended December 31, 2021, primarily due to the increase in foreign exchange loss of RMB5.9 million mainly as a result of the depreciation of U.S. dollars we received through pre-[**REDACTED**] investments in 2021.

Finance costs

Our finance costs were RMB11.8 million and RMB11.6 million for the year ended December 31, 2020 and 2021, respectively, and remained stable.

Loss before tax

As a result of the foregoing, our loss before tax decreased by 6.3% from RMB240.5 million for the year ended December 31, 2020 to RMB225.4 million for the year ended December 31, 2021.

Income tax expense

As we were loss-making for the years ended December 31, 2020 and 2021, we did not incur income tax expenses.

Loss for the year

As a result of the foregoing, our loss for the year decreased by 6.3% from RMB240.5 million for the year ended December 31, 2020 to RMB225.4 million for the year ended December 31, 2021.

DESCRIPTION OF MAJOR LINE ITEMS IN OUR CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated, which has been extracted from the Accountants' Report set out in Appendix I to this document:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Total current assets	92,062	939,850	762,448
Total non-current assets	815,968	1,166,754	1,262,928
Total assets	**908,030**	**2,106,604**	**2,025,376**
Total current liabilities	396,177	260,482	313,341
Total non-current liabilities	30,264	294,435	303,485
Total liabilities	**426,441**	**554,917**	**616,826**
Net current (liabilities)/assets	**(304,115)**	**679,368**	**449,107**
Net assets	**481,589**	**1,551,687**	**1,408,550**
Share capital	–	498,583	498,583
Paid-in capital	360,000	–	–
Reserves	121,589	1,053,104	909,967
Total equity	**481,589**	**1,551,687**	**1,408,550**

The following table sets forth a breakdown of our current assets and current liabilities as of the dates indicated, which has been extracted from the Accountants' Report set out in Appendix I to this document:

	As of December 31,		As of June 30,	As of October 31,
	2020	2021	2022	2022
	(RMB in thousands)			(unaudited)
CURRENT ASSETS				
Inventories	19,672	98,840	140,877	161,872
Trade and notes receivables	700	107,267	139,030	106,611
Prepayments, other receivables and other assets	68,061	75,328	68,112	58,601
Pledged deposits	–	44,853	2,188	1,755
Time deposits over three months	–	81,859	100,000	–
Cash and cash equivalents	3,629	531,703	312,241	269,866
Total current assets	**92,062**	**939,850**	**762,448**	**598,705**
CURRENT LIABILITIES				
Lease liabilities	7,647	10,019	9,980	9,426
Trade and notes payables	91,585	138,714	120,539	143,275
Other payables and accruals	12,187	79,024	151,318	180,085
Interest-bearing bank loans	–	10,000	26,680	54,885
Due to related parties	284,758	22,725	4,824	10,366
Total current liabilities	**396,177**	**260,482**	**313,341**	**398,037**
NET CURRENT (LIABILITIES)/ASSETS	**(304,115)**	**679,368**	**449,107**	**200,668**

We had net current liabilities of RMB304.1 million as of December 31, 2020, primarily attributable to (i) due to related parties of RMB284.8 million mainly representing the loans from Shandong Luye and (ii) trade and notes payables of RMB91.6 million mainly in connection with our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process, partially offset by prepayments, other receivables and other assets of RMB68.1 million primarily attributable to prepayments in connection with our purchase of raw materials used and related expenses for research and development activities, and raw materials used for pilot and commercial production as well as value added tax (the "**VAT**") recoverable. We had net current assets of RMB679.4 million as of December 31, 2021, primarily due to cash and cash equivalents of RMB531.7 million mainly attributable to the proceeds we received through pre-[**REDACTED**] investments and trade and notes receivables of RMB107.3 million mainly related to our sales of Boyounuo® (BA1101),

partially offset by (i) trade and notes payables of RMB138.7 million mainly reflecting our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process and (ii) other payables and accruals of RMB79.0 million mainly reflecting (a) accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) and (b) payroll payables. We had net current assets of RMB449.1 million as of June 30, 2022, primarily due to (i) cash and cash equivalents of RMB312.2 million mainly attributable to the proceeds we received through pre-[**REDACTED**] investments and from the sales of Boyounuo® (BA1101), (ii) inventories of RMB140.9 million consisting of raw materials used in manufacturing processes for our drug products as well as work in progress and finished goods and (iii) trade and notes receivables of RMB139.0 million mainly related to our sales of Boyounuo® (BA1101), partially offset by (i) other payables and accruals of RMB151.3 million mainly reflecting (a) accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) and (b) payroll payables and (ii) trade and notes payables of RMB120.5 million mainly reflecting our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process. As of October 31, 2022, being the latest practicable date for ascertaining certain financial information of our Group, we had net current assets of RMB200.7 million mainly attributable to (i) cash and cash equivalents of RMB269.9 million mainly attributable to the proceeds we received through pre-[**REDACTED**] investments and the revenue from the sales of Boyounuo® (BA1101), (ii) inventories of RMB161.9 million consisting of raw materials used in manufacturing processes for our drug products as well as work in progress and finished goods and (iii) trade and notes receivables of RMB106.6 million mainly related to our sales of Boyounuo® (BA1101), partially offset by (i) other payables and accruals of RMB180.1 million mainly reflecting (a) accrued promotion expenses representing promotion expenses payable mainly in connection with the sales of Boyounuo® (BA1101) and (b) payroll payables and (ii) trade and notes payables of RMB143.3 million mainly reflecting our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process.

Inventories

Our inventories primarily consist of raw materials used in manufacturing processes for our drug products, work in progress and finished goods. The following table sets forth a breakdown of our inventories as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Raw materials	19,672	53,926	98,068
Work in progress	–	12,525	28,602
Finished goods	–	32,389	14,207
Total	**19,672**	**98,840**	**140,877**

Our inventories increased significantly from RMB19.7 million as of December 31, 2020 to RMB98.8 million as of December 31, 2021, primarily due to the sales of Boyounuo® (BA1101) from May 2021 for which we increased procurement of raw materials to meet future demands for Boyounuo® (BA1101) and we had work in progress and finished goods of the drug product. Our inventories further increased to RMB140.9 million as of June 30, 2022, primarily due to the increases in raw materials and work in progress as a result of our continued procurement of raw materials (i) for the production and sales of Boyounuo® (BA1101) and (ii) to strategically mitigate the risks associated with supply chain disruption caused by the COVID-19.

The average turnover days of our inventories are calculated as the arithmetic mean of the beginning and ending balances of our inventories divided by the sum of cost of sales for that period and multiplied by 360 days or 180 days for that period. The average turnover days of our finished goods are calculated as the arithmetic mean of the beginning and ending balances of our finished goods divided by the sum of cost of sales for that period and multiplied by 360 days or 180 days for that period. The average turnover days of our inventories and finished goods in 2021 were 408.7 days and 111.7 days, respectively, as a result of the sales of Boyounuo® (BA1101) that commenced in May 2021. The average turnover days of our inventories and our finished goods for the six months ended June 30, 2022 decreased to 293.8 days and 57.1 days, respectively, mainly due to the increased sales of Boyounuo® (BA1101).

Our inventories are stated at the lower of cost and net realizable value. Cost is determined on the weighted average basis and, in the case of work in progress and finished goods, comprises direct materials, direct labor and an appropriate proportion of overheads. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal. As of December 31, 2020 and 2021 and June 30, 2022, we did not discover any recoverability issue for our inventories, after we assessed whether there was any inventories impaired due to factors such as damage, obsolescence or declining selling prices, by comparing the carrying amount of inventories with their net realizable values, and therefore we had minimal provision for the inventories as of the respective dates, which we considered to be sufficient.

As of October 31, 2022, RMB107.6 million, representing 76.4% of the inventories as of June 30, 2022 was subsequently utilized.

Trade and notes receivables

Our trade and notes receivables primarily consist of (i) trade receivables mainly representing receivables due from our customers, namely, third-party distributors, in connection with the sales of Boyounuo® (BA1101) and (ii) notes receivables mainly representing (i) a bank acceptance bill of RMB0.7 million we received from a related party as of December 31, 2020 which was later settled in 2021 and (ii) notes from our customers of Boyounuo® (BA1101) used to settle their payment due to us.

The following table sets forth a breakdown of our trade and notes receivables as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Trade receivables	–	78,057	109,848
Notes receivables	700	29,210	29,208
Impairment	–	–	(26)
Total	**700**	**107,267**	**139,030**

Our trade receivables increased from nil as of December 31, 2020 to RMB78.1 million as of December 31, 2021, and our notes receivables increased significantly from RMB0.7 million as of December 31, 2020 to RMB29.2 million as of December 31, 2021 both primarily due to the sales of Boyounuo® (BA1101) that commenced in May 2021.

Our trade and notes receivables increased by 29.6% from RMB107.3 million as of December 31, 2021 to RMB139.0 million as of June 30, 2022 primarily due to the increase in our trade receivables from RMB78.1 million as of December 31, 2021 to RMB109.8 million as of June 30, 2022 mainly attributable to the sales of Boyounuo® (BA1101).

We generally grant our customers credit terms of one to three months, depending on the specific payment terms in each contract. We may require prepayments from our customers before product deliveries from a credit control perspective. See "Business — Commercialization, sales, marketing and distribution — Terms of distribution agreements" for further details. We seek to maintain strict control over our outstanding receivables and have a credit control department to minimize credit risk. Our senior management reviewed overdue balances regularly. In view of the aforementioned and the fact that our trade receivables relate to a large number of diversified customers, there is no significant concentration of credit risk. We do not hold any collateral or other credit enhancements over our trade receivable balances. Trade receivables are non-interest-bearing.

The average trade receivables turnover days are calculated as the arithmetic mean of the beginning and ending trade receivables balances divided by revenue for that period and multiplied by 240 days for the relevant period in 2021 representing about eight months of our sales of Boyounuo® (BA1101) in 2021 or by 180 days for the six months ended June 30, 2022. The average trade receivables turnover days increased from 59.0 days for eight months ended December 31, 2021 to 76.6 days for the six months ended June 30, 2022, which was in line with the credit period we granted to our customers, primarily because we had a significant increase in the beginning trade receivables balance in 2022 from sales of Boyounuo® (BA1101).

As of October 31, 2022, RMB83.9 million, representing 76.4% of the trade receivables as of June 30, 2022 was subsequently settled.

The following table sets forth an aging analysis based on the invoice date of our trade receivables, net of loss allowance, as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Within 3 months	–	77,858	79,933
3 to 6 months	–	113	1,061
6 to 12 months	–	86	28,803
1 to 2 years	–	–	25
Total	**–**	**78,057**	**109,822**

As of December 31, 2020 and 2021 and June 30, 2022, we monitor our trade and notes receivables on an ongoing basis. We performed the impairment analysis as of December 31, 2020 and 2021 and June 30, 2022 using a provision matrix to measure expected credit losses. As of December 31, 2020 and 2021 and June 30, 2022, our loss allowance for impairment of trade receivables amounted to nil, nil and RMB26,000, respectively. The loss allowance is calculated by multiplying the trade receivables balance by the expected credit loss rate. Different expected credit loss rate is applied to the balance of each age-band for the trade receivables. For example, our loss allowance as of June 30, 2022 amounted to RMB26,000, calculated by multiplying the trade receivables balance aged from one year to two years by the expected credit loss rate applied to the trade receivables in such age-band, which is 50.0%. The expected credit loss rate applied to the trade receivables aged within one year was zero. Specifically, for our trade receivables of RMB28.8 million aged between six to 12 months, because they are not overdue, we do not consider there is any recoverability issue and therefore there has been no provision made for them. The expected credit loss rates are based on ageing for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome and reasonable and supportable information that is available at the end of the reporting period about past events, current conditions and forecasts of future economic conditions. For further details on the credit risk exposure on our trade receivables using a provision matrix, please refer to Note 17 to the Accountants' Report as set out in Appendix I to this document. We did not discover any significant recoverability issue for our trade and notes receivables, after our periodic assessment based on historical settlement records, past experience and certain forward-looking information, together with our policy of only trading with recognized and creditworthy third parties and our adherence to credit verification procedures, and therefore we had minimal provision for the trade and notes receivables as of the respective dates, which we considered to be sufficient.

Prepayments, other receivables and other assets

Our prepayments, other receivables and other assets primarily represent (i) prepayments in connection with our purchase of raw materials used and related expenses for research and development activities as well as raw materials used for pilot and commercial production, (ii) VAT recoverable, being the difference between the input VAT and output VAT, which mainly relate to our procurement of supplies which may be credited against future VAT payable for our sales of products, (iii) other receivables which mainly represent (a) Phase 3 clinical trial costs of BA9101 to be received from OcuMension, (b) the social insurance premium contributions and housing provident funds we paid for our employees, (c) interest of time deposits and (d) the advances to employees for business purpose, (iv) deferred [**REDACTED**] expenses which mainly represent the capitalized [**REDACTED**] expenses and (v) other current assets which mainly represent raw materials and consumables used in R&D activities. The following table sets forth a breakdown of our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Prepayments	33,738	51,592	54,624
Value-added tax recoverable	29,840	15,472	4,642
Other receivables	400	2,813	660
Deferred [**REDACTED**] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Other current assets	4,083	5,033	4,559
Total	**68,061**	**75,328**	**68,112**

Our prepayments, other receivables and other assets increased by 10.7% from RMB68.1 million as of December 31, 2020 to RMB75.3 million as of December 31, 2021 primarily due to the increase in prepayments from RMB33.7 million as of December 31, 2020 to RMB51.6 million as of December 31, 2021 mainly in connection with (i) purchase of raw materials for the production of Boyounuo® (BA1101) and our product candidates and (ii) R&D expenses for our increasing research projects, partially offset by the decrease in value-added tax recoverable from RMB29.8 million as of December 31, 2020 to RMB15.5 million as of December 31, 2021 mainly due to (i) the decrease in the non-deductible input VAT in relation to Boyounuo® (BA1101) which was accounted for as other line items such as cost of sales or research and development costs after the commercialization of Boyounuo® (BA1101) and (ii) our receipt of VAT refund in relation to the research projects other than Boyounuo® (BA1101). Our prepayments, other receivables and other assets decreased by 9.6% from RMB75.3 million as of December 31, 2021 to RMB68.1 million as of June 30, 2022 primarily due to the decrease in value-added tax recoverable from RMB15.5 million as of December 31, 2021 to RMB4.6 million as of June 30, 2022 mainly due to the tax credit we claimed that offset the value-added tax recoverable, partially offset by the

increases in (i) prepayments from RMB51.6 million as of December 31, 2021 to RMB54.6 million as of June 30, 2022 mainly in connection with (a) purchase of raw materials for the production of Boyounuo® (BA1101) and our product candidates and (b) R&D expenses related to the Phase 3 clinical trial of BA1102 and (ii) deferred [**REDACTED**] expenses from RMB[**REDACTED**] as of December 31, 2021 to RMB[**REDACTED**] as of June 30, 2022 mainly in connection with the proposed [**REDACTED**].

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As of December 31, 2020 and 2021 and June 30, 2022, the loss allowance of our Group was assessed to be minimal.

As of October 31, 2022, RMB34.8 million, representing 63.7% of the prepayments as of June 30, 2022 was subsequently settled.

Cash and cash equivalents

Our cash and cash equivalents primarily represent cash and bank balances and time deposits. Our cash at banks earns interest at floating rates based on daily bank deposit rates. The following table sets forth a breakdown of our cash and cash equivalents as of the dates indicated:

	As of December 31,		As of June 30,
	2020	**2021**	**2022**
	(RMB in thousands)		
Cash and bank balances	3,629	558,415	314,429
Time deposits	–	100,000	100,000
Less:			
Pledged deposits for notes payable	–	(44,853)	(2,188)
Non-pledged time deposits over three months	–	(81,859)	(100,000)
Cash and cash equivalents	3,629	531,703	312,241
Denominated in:			
RMB	3,629	281,308	297,805
United States dollar	–	250,094	14,034
Singapore dollar	–	301	402
Total	**3,629**	**531,703**	**312,241**

Our cash and cash equivalents increased significantly from RMB3.6 million as of December 31, 2020 to RMB531.7 million as of December 31, 2021 primarily due to the proceeds we received through pre-[**REDACTED**] investments. Our cash and cash equivalents decreased by 41.3% from RMB531.7 million as of December 31, 2021 to RMB312.2 million as of June 30, 2022 primarily due to cash used in operating activities, increase in intangible assets mainly reflecting the capitalization of the research and development costs related to BA1102, BA9101 and BA6101 and purchases of property, plant and equipment mainly related to the new production lines. All of our cash and cash equivalents were denominated in RMB as of December 31, 2020. We had cash and cash equivalents of RMB281.3 million denominated in Renminbi, RMB250.1 million denominated in U.S. dollar and RMB0.3 million denominated in Singapore dollar as of December 31, 2021. Such increase in foreign currencies were mainly attributable to the proceeds we received through pre-[**REDACTED**] investments. We had cash and cash equivalents of RMB297.8 million denominated in Renminbi, RMB14.0 million denominated in U.S. dollar and RMB0.4 million denominated in Singapore dollar as of June 30, 2022. Such decrease in United States dollar was because we converted United States dollar into Renminbi in anticipation of the further depreciation of United States dollar.

Our pledged deposits for notes payable represent the deposits we pledged to a bank as collateral for our banking facilities used to settle our notes payables. Under the pledge agreement, we agreed to provide security for our obligations under a series of banking facilities, including but not limited to issuance of bank acceptance bills and discounted notes receivable, to the Lai Shan branch of Hengfeng Bank Co., Ltd. ("**Hengfeng Bank**") within the maximum balance of a certificate of deposits in the amount of RMB100.0 million (the "**Certificate of Deposits**"). In the event that we fail to repay under those banking facilities, Hengfeng Bank shall have the right to be repaid as first priority under the pledge. Upon the settlement of our obligations under certain banking facilities, the corresponding amount of the pledged deposits will be released. Our pledged deposits for notes payable increased from nil as of December 31, 2020 to RMB44.9 million as of December 31, 2021, and then decreased to RMB2.2 million as of June 30, 2022, which were in line with the balance of our notes payables. Our non-pledged time deposits over three months represent the non-pledged portion of the Certificate of Deposits we acquired in 2021 from an Independent Third party with a remaining maturity of less than one year as of December 31, 2021 to enjoy a higher interest rate. The Certificate of Deposits originally has a term of three years due on December 20, 2022. It bears an interest rate of 4.18% and the interests are receivable quarterly. According to the agreement of the Certificate of Deposits, such deposits are transferrable, irredeemable and cannot be withdrawn early. Our non-pledged time deposits over three months increased from RMB81.9 million as of December 31, 2021 to RMB100.0 million as of June 30, 2022, which was mainly attributable to the release of pledged deposits upon the settlement of such banking facilities.

Trade and notes payables

Our trade and notes payables primarily consist of trade payables and notes payables in connection with our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process.

The following table sets forth a breakdown of our trade and notes payables as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Trade payables	91,585	93,861	118,351
Notes payable	–	44,853	2,188
Total	**91,585**	**138,714**	**120,539**

Our trade and notes payables increased by 51.5% from RMB91.6 million as of December 31, 2020 to RMB138.7 million as of December 31, 2021, which was primarily due to the increase in notes payable from nil as of December 31, 2020 to RMB44.9 million as of December 31, 2021, which were in line with our expansion of business and the sales of Boyounuo® (BA1101) and the fact that we used notes as our payment method in 2021. Our trade and notes payables decreased by 13.1% from RMB138.7 million as of December 31, 2021 to RMB120.5 million as of June 30, 2022, which was primarily due to the decrease in notes payable from RMB44.9 million as of December 31, 2021 to RMB2.2 million as of June 30, 2022, primarily due to our repayment upon due , partially offset by the increase in trade payables from RMB93.9 million as of December 31, 2021 to RMB118.4 million as of June 30, 2022, primarily reflecting our increased procurement of raw materials used and incurrence of related expenses for research and development activities and pilot and commercial production process.

The maturity of our notes payable is within six months. Our trade payables are non-interest-bearing and are normally settled on 90-day terms. The following table sets forth an aging analysis based on the invoice date of our trade payables as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Within 3 months	83,102	75,185	97,889
3 to 6 months	5,084	8,453	13,134
6 to 12 months	3,184	5,593	5,589
1 to 2 years	198	4,548	941
Over 2 years	17	82	798
Total	**91,585**	**93,861**	**118,351**

As of October 31, 2022, RMB47.9 million, representing 40.5% of the trade payables as of June 30, 2022 was subsequently settled.

The average trade payables turnover days are calculated as the arithmetic mean of the beginning and ending trade payables balances divided by the sum of cost of sales and research and development costs for that period and multiplied by 360 days or 180 days for that period. The average trade payables turnover days increased from 99.6 days in 2020 to 117.6 days in 2021 primarily because we had a significant increase in trade payables in 2020 compared to a smaller increase in trade payables in 2021 mainly reflecting different level of increases in clinical trial expense. The average trade payables turnover days decreased from 117.6 days in 2021 to 78.8 days for the six months ended June 30, 2022 primarily because (i) we had a significant increase in the research and development costs mainly in relation to our research projects such as the R&D of BA1301 that commenced in May 2021, (ii) we only incurred cost of sales for about eight months for our sales of Boyounuo® (BA1101) in 2021 and (iii) our trade payables increased at a slower pace than the cost of sales as we used cash payments more frequently than before.

Other payables and accruals

Our other payables and accruals primarily consist of (i) payroll payables, (ii) other payables mainly consisting of payables for purchase of machinery and equipment, (iii) taxes payable other than income tax mainly representing VAT in connection with our sales of Boyounuo® (BA1101), (iv) accrued promotion expenses mainly in connection with product promotion services provided by independent third-party promoters, (v) accrued [**REDACTED**] expenses for the proposed [**REDACTED**] and (vi) contract liabilities mainly including short-term advances received to deliver products. The following table sets forth a breakdown of our other payables and accruals as of the dates indicated:

	As of December 31,		As of June 30,
	2020	**2021**	**2022**
	(RMB in thousands)		
Payroll payables	6,355	21,408	21,785
Other payables	5,538	7,509	9,621
Taxes payable other than income tax	294	5,870	10,169
Accrued promotion expenses	–	42,305	90,562
Accrued [**REDACTED**] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Contract liabilities	–	1,290	3,393
Total	**12,187**	**79,024**	**151,318**

Our other payables and accruals increased significantly from RMB12.2 million as of December 31, 2020 to RMB79.0 million as of December 31, 2021, primarily due to the increases in (i) accrued promotion expenses from nil as of December 31, 2020 to RMB42.3 million as of December 31, 2021 mainly attributable to the promotion expenses payable in connection with the sales of Boyounuo® (BA1101) and (ii) payroll payables from RMB6.4 million as of December 31, 2020 to RMB21.4 million as of December 31, 2021 mainly due to the increase in staff headcount as we ramped up our business operation and R&D, sales and marketing activities. Our other payables and accruals increased by 91.5% from RMB79.0 million as of December 31, 2021 to RMB151.3 million as of June 30, 2022, primarily due to the increases in accrued promotion expenses from RMB42.3 million as of December 31, 2021 to RMB90.6 million as of June 30, 2022, mainly in connection with the sales of Boyounuo® (BA1101) as well as accrued [**REDACTED**] expenses for the proposed [**REDACTED**] from RMB[**REDACTED**] as of December 31, 2021 to RMB[**REDACTED**] as of June 30, 2022.

Property, plant and equipment

Our property, plant and equipment primarily consists of (i) buildings, (ii) machinery and equipment, (iii) office equipment and (iv) construction in progress mainly representing our machinery and equipment under installation in relation to our new production lines. The following table sets forth a breakdown of our property, plant and equipment as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Buildings	121,017	117,164	115,303
Machinery and equipment	337,850	368,401	392,926
Office equipment	1,566	6,835	6,618
Construction in progress	1,737	12,442	47,803
Total	**462,170**	**504,842**	**562,650**

Our property, plant and equipment increased by 9.2% from RMB462.2 million as of December 31, 2020 to RMB504.8 million as of December 31, 2021, primarily attributable to the increase in machinery and equipment from RMB337.9 million as of December 31, 2020 to RMB368.4 million as of December 31, 2021 mainly as a result of the increased machinery and equipment for research and development activities. Our property, plant and equipment increased by 11.5% from RMB504.8 million as of December 31, 2021 to RMB562.7 million as of June 30, 2022, primarily attributable to the increases in (i) construction in progress from RMB12.4 million as of December 31, 2021 to RMB47.8 million as of June 30, 2022 mainly in relation to our new production lines and (ii) machinery and equipment from RMB368.4 million as of December 31, 2021 to RMB392.9 million as of June 30, 2022 mainly in relation to our new production lines.

Intangible assets

Our intangible assets primarily consist of (i) technology know-how mainly representing proprietary technology, (ii) software and (iii) deferred development costs mainly representing the expenditure incurred for our drug candidates which were eligible for capitalization. The following table sets forth a breakdown of our intangible assets as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Technology know-how	**11,700**	**8,100**	**6,300**
Deferred development costs	**313,531**	**557,871**	**646,881**
– Boyounuo® (BA1101)	234,341	271,878	264,958
– BA6101(1)	73,564	171,085	183,474
– BA1102(2)	–	74,601	119,989
– BA9101	5,626	40,307	78,460
Software	**35**	**31**	**29**
Total	**325,266**	**566,002**	**653,210**

Notes:

(1) For the years ended December 31, 2020 and 2021, and the six months ended June 30, 2022, the capitalized R&D expenditures on BA6101 were RMB59.5 million, RMB97.5 million and RMB12.4 million, respectively.

(2) For the years ended December 31, 2020 and 2021, and the six months ended June 30, 2022, the capitalized R&D expenditures on BA1102 were nil, RMB74.6 million and RMB45.4 million, respectively.

Our intangible assets increased from RMB325.3 million as of December 31, 2020 to RMB566.0 million as of December 31, 2021, primarily attributable to the increase in deferred development costs from RMB313.5 million as of December 31, 2020 to RMB557.9 million as of December 31, 2021 mainly as a result of the capitalization of the research and development costs related to BA6101, BA1102, Boyounuo® (BA1101) and BA9101 as deferred development cost in 2021. Our intangible assets increased by 15.4% from RMB566.0 million as of December 31, 2021 to RMB653.2 million as of June 30, 2022, primarily attributable to the increase in deferred development costs from RMB557.9 million as of December 31, 2021 to RMB646.9 million as of June 30, 2022 mainly as a result of the capitalization of the research and development costs related to BA1102, BA9101 and BA6101 as deferred development cost.

For the year ended 31 December 2020, no amortization was provided for deferred development costs as the related intangible assets were not available for use and the software was acquired in December 2020 with its amortization amount close to zero.

Impairment testing of deferred development costs

Our management tests the deferred development costs which are not yet available for use for impairment at least annually, and whenever there is an indication that the unit may be impaired, by comparing their carrying amount with their recoverable amounts.

The recoverable amounts of the deferred development costs were determined based on the value in use. The value in use of the deferred development costs was determined by using the risk-adjusted net present value method through taking into account the possibility of success, using cash flow projections based on financial budgets approved by our management covering fourteen to fifteen years which consist of development periods up to three years, growth and mature periods of seven to ten years and fast-declining periods of five years, reflecting the periods before reaching a perpetual growth mode. Considering it generally takes longer for a biotechnology company to reach a perpetual growth mode compared to companies in other industries and taking into account of the expected timing of commercialisation, market size and penetration of related products, we prepared the financial forecasts up to the year of 2035 in the impairment tests. Other key assumptions used in the value-in-use calculations are listed as follows:

	December 31, 2020	**December 31, 2021**
Discount rates	15%	15%
Budgeted gross margins	86%	86%
Terminal growth rates	-3%	-3%

Discount rates — The discount rates used are before tax and reflect specific risks relating to deferred development costs.

Budgeted gross margins — The basis used to determine the value assigned to budgeted gross margins is the market gross margins where the biopharmaceuticals are located, taking into account the expected efficiency improvements and expected market development.

Terminal growth rates — The terminal growth rates used to extrapolate the cash flows beyond the forecast period are based on the estimate to the life cycle of biosimilars and the characteristics of biopharmaceuticals.

As of December 31, 2020 and 2021, the recoverable amount of deferred development costs and the carrying amount of each project are listed as follows:

	Recoverable amounts *RMB'000*	**Carrying amounts** *RMB'000*	**Headroom** *RMB'000*
December 31, 2020			
BA1101	1,399,830	234,341	1,165,489
BA6101	182,680	73,564	109,116
BA9101	80,945	5,626	75,319
	1,663,455	313,531	1,349,924
December 31, 2021			
BA6101	294,610	171,085	123,525
BA9101	96,626	40,307	56,319
BA1102	104,565	74,601	29,964
	495,801	285,993	209,808

We did not perform impairment test for deferred development costs as of June 30, 2022, because there was no indication that any project might be impaired as at 30 June 2022, and we perform impairment test annually at December year-end in accordance with IAS 36 *Impairment of assets*.

Sensitivity to changes in key assumptions

The following table sets forth the impact of reasonably possible changes in each of the key assumptions on, with all other variables held constant, impairment testing of our deferred development costs as of the dates indicated.

	Recoverable amount of the deferred development costs exceeding their carrying amount decrease by	
	December 31, 2020 *RMB'000*	**December 31, 2021** *RMB'000*
Possible changes of key assumptions		
Discount rates increased by 1%	99,439	33,653
Budgeted gross margins decreased by 1%	37,525	17,939
Terminal growth rate decreased by 1%	3,851	1,585
Expected market shares decreased by 1%	102,273	10,489

With regard to the assessment of value in use, we believe that no reasonably possible changes in any of the key assumptions would cause the recoverable amounts of deferred development costs to be materially lower than their carrying amounts.

Interest-bearing bank loans

See "— Indebtedness — Interest-bearing bank loans" in this section for further details.

Lease liabilities

See "— Indebtedness — Lease liabilities" in this section for further details.

Government grants

We receive certain government grants primarily representing subsidies received from local government authorities to support the Group's research and development activities and operation. To the extent any requirement or condition attached to such government grants has not been met, we record such portion of government grants under liabilities. Our government grants recorded under non-current liabilities decreased by 35.7% from RMB2.8 million as of December 31, 2020 to RMB1.8 million as of December 31, 2021, primarily because a government grant of RMB1.0 million related to our clinical research on Boyounuo® (BA1101) was recognized in profit or loss when its conditions were met in 2021. Our government grants recorded under non-current liabilities decreased from RMB1.8 million as of December 31, 2021 to nil as of June 30, 2022, primarily because a government grant of RMB1.8 million related to our research and development on LY-CovMab was recognized in profit or loss when its conditions were met.

The following table sets forth the amounts of the government grants recorded under liabilities as of the dates indicated:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
At beginning of the year/period	1,200	2,800	1,800
Grants received during the year/period	1,800	–	–
Amounts released to profit or loss	(200)	(1,000)	(1,800)
At end of the year/period	**2,800**	**1,800**	**–**

Other non-current liabilities

We entered into an agreement with OcuMension on October 28, 2020, as amended by a supplemental agreement dated May 31, 2021, pursuant to which we are responsible for conducting certain initial stages of the Phase 3 clinical trial and commercial production as well as submitting the BLA of BA9101 and OcuMension is responsible for completing the rest of Phase 3 clinical trial and promoting and commercializing BA9101 in China. Other non-current liabilities represent the considerations we received from OcuMension for our collaboration arrangement. Our other non-current liabilities increased significantly from RMB19.0 million as of December 31, 2020 to RMB48.1 million as of December 31, 2021, and further increased by 60.3% to RMB77.2 million as of June 30, 2022, primarily attributable to the increase in the considerations received from OcuMension for BA9101.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of liquidity consist of cash and cash equivalents, which we have historically generated primarily through pre-[**REDACTED**] investments and bank loans. We expect that our cash needs in the near future will primarily relate to progressing the development of our drug candidates towards receiving regulatory approval and commencing commercialization, as well as expanding our drug candidate portfolio. For these purposes, we expect debt financing including bank loans and the expected [**REDACTED**] from the [**REDACTED**] to constitute the main source of funding. We also expect product sales from Boyounuo® (BA1101), for which we received regulatory approval in April 2021 and commenced commercial sales in May 2021, to continue to generate operational cash flow onwards. Moreover, we may consider increasing our debt financing or undertaking further placements in order to undertake activities which require substantial capital expenditure, subject to pricing and other market conditions that we consider satisfactory. We monitor our cash flows and cash balance on a regular basis and strive to maintain an optimal liquidity that can meet our working capital needs.

Cash operating costs

The following table sets forth the breakdown of our cash operating costs for the periods indicated:

	Years ended December 31,		Six months ended June 30,
	2020	2021	2022
	(RMB in thousands)		
Costs Relating to Research and Development of Our Core Product Candidates			
R&D service fees	74,426	78,316	14,586
Raw material costs	59,246	27,366	13,545
Salaries and benefits	13,719	22,008	9,179
Subtotal	**147,391**	**127,690**	**37,310**
Costs Relating to Research and Development of Our Other Product Candidates			
R&D service fees	101,652	110,988	60,487
Raw material costs	50,643	58,702	41,549
Salaries and benefits	17,438	37,350	21,382
Subtotal	**169,733**	**207,040**	**123,418**
Product Marketing	**–**	**6,761**	**42,006**
Workforce Employment[(1)]	**1,541**	**30,779**	**19,026**
Non-income Taxes, Royalties and Other Government Charges	**1,784**	**15,458**	**5,084**
Direct Production Costs	**–**	**20,826**	**12,415**
Contingency Allowances	**–**	**–**	**–**
Total	**320,449**	**408,553**	**239,259**

Note:

(1) Workforce employment costs represent total non-R&D staff costs mainly including salaries, bonus and benefits.

Cash flows

The following table sets forth our cash flows for the periods indicated:

	Years ended December 31,		Six months ended June 30,	
	2020	**2021**	**2021**	**2022**
	(RMB in thousands)		(unaudited)	
Operating cash flow before movements in working capital	(214,021)	(146,620)	(101,412)	(108,061)
Change in working capital	(292,699)	(99,658)	(50,279)	(6,151)
Net cash flows used in operating activities	(506,720)	(246,278)	(151,691)	(114,212)
Net cash flows used in investing activities	(18,787)	(432,296)	(260,223)	(97,604)
Net cash flows from/(used in) financing activities	527,233	1,211,729	1,016,220	(11,462)
Net increase/(decrease) in cash and cash equivalents	**1,726**	**533,155**	**604,306**	**(223,278)**
Cash and cash equivalents at the beginning of the year/period	1,903	3,629	3,629	531,703
Effect of foreign exchange rate changes, net	–	(5,081)	(462)	3,816
Cash and cash equivalents at the end of the year/period	**3,629**	**531,703**	**607,473**	**312,241**

Net cash used in operating activities

During the Track Record Period, we have incurred negative cash flows from our operations. Net cash used in operating activities primarily comprises our loss before tax for the period adjusted by (i) non-operating items and non-cash items; and (ii) changes in working capital. We expect to improve our net operating cash outflows position through, among others, (i) increasing the revenue from sales of our existing drug and drug candidates in the event of successful commercialization, (ii) accelerating our late-stage pipeline products towards commercialization to generate revenue from product sales, (iii) adopting measures to effectively control our cost and operating expenses, primarily including research and development costs, administrative expenses and sales and distribution expenses, (iv) enhancing working capital management efficiency, and (v) successfully launching the [**REDACTED**] to obtain the [**REDACTED**].

For the six months ended June 30, 2022, we had net cash used in operating activities of RMB114.2 million. We had operating cash outflow before movements in working capital of RMB108.1 million, primarily consisting of loss before tax of RMB153.3 million, as adjusted for (i) depreciation of property, plant and equipment of RMB23.3 million, (ii) share-based payment expense of RMB9.1 million in connection with our ESOP and (iii) amortization of intangible assets of RMB8.2 million. Movements in working capital resulted in a net cash outflow of RMB6.2 million, primarily consisting of (i) increase in inventories of RMB42.0 million, (ii) increase in trade and notes receivables of RMB31.8 million mainly reflecting the increased revenue from the sales of Boyounuo® (BA1101), (iii) decrease in trade and notes payables of RMB18.2 million mainly reflecting the settlement of such amount and (iv) decrease in amounts due to related parties of RMB17.9 million mainly due to the settlement of such amount, partially offset by (i) increase in other payables and accruals of RMB70.7 million mainly reflecting accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) as well as accrued [**REDACTED**] expenses for the proposed [**REDACTED**] and (ii) decrease in pledged deposits of RMB24.5 million attributable to the release of pledged deposits upon the settlement of such banking facilities.

For the year ended December 31, 2021, we had net cash used in operating activities of RMB246.3 million. We had operating cash outflow before movements in working capital of RMB146.6 million, primarily consists of loss before tax of RMB225.4 million, as adjusted for (i) depreciation of property, plant and equipment of RMB30.9 million, (ii) share-based payment expense of RMB21.3 million in connection with our ESOP, (iii) finance costs of RMB11.6 million primarily consisting of interest on our loans and borrowings and (iv) amortization of intangible assets of RMB11.0 million. Movements in working capital resulted in a net cash outflow of RMB99.7 million, primarily consisting of an increase in trade and notes receivables of RMB106.6 million and inventories of RMB79.2 million, partially offset by increases in (i) other payables and accruals of RMB64.2 million mainly reflecting (a) accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) as well as accrued [**REDACTED**] expenses for the proposed [**REDACTED**] and (b) payroll payables and (ii) trade and notes payables of RMB47.1 million in connection with our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process.

For the year ended December 31, 2020, we had net cash used in operating activities of RMB506.7 million. We had operating cash outflow before movements in working capital of RMB214.0 million, primarily consisting of loss before tax of RMB240.5 million, as adjusted for finance costs of RMB11.8 million primarily consisting of interest on our loans and borrowings and depreciation of property, plant and equipment of RMB10.5 million. Movements in working capital resulted in a net cash outflow of RMB292.7 million, primarily consisting of (i) a decrease in amounts due to related parties of RMB327.4 million due to its settlement and (ii) an increase in prepayments, other receivables and other assets of RMB22.9 million due to prepayments mainly in connection with our purchase of raw materials used and related expenses for research and development activities as well as raw materials used for pilot and commercial production, partially offset by increases in (i) trade and notes payables of RMB52.4 million due to our purchase of raw materials used and related expenses for research and development activities and pilot and commercial production process and (ii) other non-current liabilities of RMB19.0 million representing the considerations received from OcuMension for BA9101.

Net cash used in investing activities

For the six months ended June 30, 2022, we had net cash used in investing activities of RMB97.6 million, primarily representing (i) additions to intangible assets of RMB62.5 million relating to the capitalization of the research and development costs related to BA1102, BA9101 and BA6101 as deferred development cost and (ii) purchases of items of property, plant and equipment of RMB39.1 million in connection with our new production lines.

For the year ended December 31, 2021, we had net cash used in investing activities of RMB432.3 million, primarily representing (i) additions to intangible assets of RMB233.5 million relating to the capitalization of the research and development costs related to BA6101, BA1102, Boyounuo® (BA1101) and BA9101 as deferred development cost in 2021, (ii) purchases and advance payments of items of property, plant and equipment of RMB107.7 million in connection with our expansion of production lines and (iii) increase in time deposits over three months of RMB100.0 million.

For the year ended December 31, 2020, we had net cash used in investing activities of RMB18.8 million, representing additions to intangible assets of RMB106.2 million mainly relating to the capitalization of the research and development costs related to Boyounuo® (BA1101) and BA6101 as deferred development cost, respectively, partially offset by the receipt of repayment from a related party of RMB112.5 million.

Net cash generated from financing activities

For the six months ended June 30, 2022, we had net cash used in financing activities of RMB11.5 million, primarily consisting of (i) our interest paid of RMB6.6 million in relation to our lease liabilities and bank loans, (ii) our repayment of the principal portion of lease payments of RMB5.6 million and (iii) our repayment of bank loans of RMB5.0 million, partially offset by the new bank loans of RMB6.7 million in relation to the discounted notes receivable to finance our operating cash flows.

For the year ended December 31, 2021, we had net cash from financing activities of RMB1,211.7 million, primarily consisting of capital contribution from shareholders of RMB1,230.2 million, partially offset by (i) our interest paid of RMB11.6 million in relation to our lease liabilities and bank loans and (ii) our repayment of the principal portion of lease payments of RMB9.4 million.

For the year ended December 31, 2020, we had net cash from financing activities of RMB527.2 million, primarily consisting of (i) advances from a related party of RMB886.1 million and (ii) capital contribution from shareholders of RMB798.3 million, partially offset by (i) repayment of advances from a related party of RMB659.1 million and (ii) repayment of bank loans of RMB485.9 million.

Working capital sufficiency

Our liquidity and capital resource needs over the next 12 months primarily relate to production and sales and marketing activities of Boyounuo® (BA1101), progressing the development of our drug candidates, the expansion of production lines and employee salaries. While we had net operating cash outflows and net losses during the Track Record Period, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents, debt financing, [**REDACTED**] from the [**REDACTED**], operating cash flows from sales of Boyounuo® (BA1101) and other funds raised from the capital markets from time to time. As of October 31, 2022, we had cash and cash equivalents of RMB269.9 million. Other than the bank borrowings that we have obtained or may obtain, we currently do not have any plans for material external debt financing. After taking into consideration the above financial resources available to us, in the absence of unforeseeable circumstances, our Directors confirm that we have sufficient working capital to satisfy at least 125% of our liquidity and capital resource needs (including research and development and administrative expenses and other operating costs, regardless of whether any such expenses and costs are capitalized) over the next 12 months from the date of this document.

Our ability to obtain additional funding beyond our anticipated cash needs for the next 12 months following the date of this document, however, is subject to a variety of uncertainties, including our future results of operations, our future business plans, financial condition and cash flows and economic, political and other conditions in the markets where we and our customers and lenders operate.

Our cash burn rate refers to the average monthly (i) net cash used in operating related activities, including research and development costs, purchase amount of property, plant and equipment as well as additions to intangible assets and (ii) net cash used in serving our indebtedness including payment of lease liabilities, loan principal and interest. As of October 31, 2022, we had cash and cash equivalents of RMB269.9 million. Assuming an average cash burn rate going forward of 1.0 times of the level in 2021 of net cash used in operating related activities and taking into account the scheduled payment of our indebtedness, we estimate that our cash and cash equivalents as of October 31, 2022 will be able to maintain our financial viability for five months, or, if we also take into account the estimated [**REDACTED**] (based on the low-end of the indicative [**REDACTED**]) from the [**REDACTED**], eight months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

INDEBTEDNESS

During the Track Record Period, we had indebtedness in the form of related parties loans, interest-bearing bank loans and lease liabilities. The following table sets forth a breakdown of our indebtedness as of the dates indicated:

	As of December 31,		As of June 30,	As of October 31,
	2020	2021	2022	2022
		(RMB in thousands)		(unaudited)
Current indebtedness				
Related-party loans				
Shandong Luye	233,824	12,780	3,594	7,405
Biotech Park Development	672	222	158	912
Geneleap Biotech LLC (formerly known as "Luye Boston Research & Development LLC") ("**Luye Boston**")	–	31	–	–
Yantai Luye	–	–	52	141
Bank loans	–	10,000	26,680	54,885
Lease liabilities	7,647	10,019	9,980	9,426
Subtotal	**242,143**	**33,052**	**40,464**	**72,769**
Non-current indebtedness				
Bank loans	–	240,000	225,000	210,000
Lease liabilities	8,486	4,504	1,323	–
Subtotal	**8,486**	**244,504**	**226,323**	**210,000**
Total	**250,629**	**277,556**	**266,787**	**282,769**

Related-party loans

Our related-party loans were mainly provided by Shandong Luye, Biotech Park Development, Luye Boston and Yantai Luye on a non-trade basis. We intend to settle the outstanding related-party loans in full by the [**REDACTED**].

Our related-party loans were unsecured, interest free and repayable on demand. The loans did not contain any financial covenants.

Interest-bearing bank loans

Our interest-bearing bank loans increased from nil as of December 31, 2020 to RMB250.0 million as of December 31, 2021, of which RMB10.0 million was current and RMB240.0 million was non-current. As of the Latest Practicable Date, we did not have unutilized banking facilities. In 2020, we had loan facilities from Bank of Qingdao Co., Ltd. Yantai Branch and Qilu Bank Co., Ltd. Yantai Branch, which were fully settled as of December 31, 2020. Our balance of interest-bearing bank loans as of December 31, 2021 was attributable to a RMB250.0 million loan facility with the Bank of China which we entered into in 2021 (the "**Bank of China Loan**"), based on which this loan shall be used to settle our shareholder loans in relation to our machinery and equipment under installation for our new production lines. The Bank of China Loan is due in 2026 and bears a floating interest rate updated per annum which is the latest five-year loan prime rate plus 5 basis points. Interests are payable quarterly. Key undertakings of the Bank of China Loan include (i) maintaining a gearing ratio of less than 90% and (ii) paying no dividends before the settlement of the Bank of China Loan. The Bank of China Loan also has mortgages over our property, plant and equipment, which had a net carrying value of approximately RMB191.8 million and our right-of-use assets, which had a net carrying value of approximately RMB4.4 million as of June 30, 2022. In addition, our related parties have guaranteed the Bank of China Loan as of June 30, 2022 and such guarantee will be released upon the [**REDACTED**]. Other terms in relation to the Bank of China Loan, such as events of default, termination rights and provisions and solvency requirements, are generally customary, and there are no other material covenants on the Bank of China Loan. Our Directors confirm that we had no material defaults in payment of interest-bearing bank and other borrowings and had not breached any material covenants thereunder during the Track Record Period and up to the Latest Practicable Date. Our Directors also confirm that we are not subject to other material covenants under any agreements with respect to any bank loans or other borrowings.

Our interest-bearing bank loans increased from RMB250.0 million as of December 31, 2021, of which RMB10.0 million was current and RMB240.0 million was non-current, to RMB251.7 million as of June 30, 2022, of which RMB26.7 million was current and RMB225.0 million was non-current. The increase in our current interest-bearing bank loans was attributable to the discounted notes receivable of RMB6.7 million because we discounted certain notes receivable to the bank prior to the notes' maturity date with effective interest rates within a range between 1.8% to 2.1% to fund our daily operations.

Interest expenses on our interest-bearing bank loans amounted to RMB11.2 million and RMB10.9 million for the years ended December 31, 2020 and 2021, respectively, and RMB5.9 million for the six months ended June 30, 2022. See note 22 to the Accountants' Report in Appendix I to this document for a breakdown of these interest-bearing bank loans.

The following table sets forth a maturity profile of our interest-bearing bank loans as of the dates indicated:

	As of December 31,		As of June 30,	As of October 31,
	2020	2021	2022	2022
		(RMB in thousands)		
				(unaudited)
Indebtedness repayable within:				
Less than one year	–	10,000	26,680	54,885
One to two years	–	30,000	40,000	50,000
Two to five years	–	210,000	185,000	160,000
Total indebtedness	**–**	**250,000**	**251,680**	**264,885**

Lease liabilities

IFRS 16 introduced a single lessee accounting model, whereby assets and liabilities are recognized for all leases on the balance sheet, subject to certain exceptions. Since IFRS 16 was adopted by our Group throughout the Track Record Period, we recognized right-of-use assets and the corresponding lease liabilities in respect of all leases, except for short-term leases and leases of low-value assets. Our lease liabilities include the present value of our lease payments as specified in note 2.3 to the Accountants' Report in Appendix I to this document.

Our lease liabilities include the properties we lease for business operations, which mainly include our office premises, laboratories, R&D and warehouse. See "Business — Land and properties" for further details. Our lease liabilities decreased by 10.0% from RMB16.1 million as of December 31, 2020 to RMB14.5 million as of December 31, 2021, and further decreased by 22.2% to RMB11.3 million as of June 30, 2022, primarily due to the rental fee paid during the relevant period. The following table sets out the carrying amount of our lease liabilities and the movements as of the dates:

	As of December 31,		As of June 30,
	2020	2021	2022
	(RMB in thousands)		
Carrying amount at January 1	8,251	16,133	14,523
New leases	8,171	9,499	2,272
Accretion of interest recognized during the year/period	597	704	264
Payments	(886)	(10,130)	(5,847)
Exemption of payments	–	(1,641)	–
Exchange realignment	–	(42)	91
Carrying amount at end of the year/period	**16,133**	**14,523**	**11,303**
Analyzed into:			
Current portion	7,647	10,019	9,980
Non-current portion	8,486	4,504	1,323

Except as disclosed above in this section, as of October 31, 2022, being our indebtedness statement date, we did not have any material mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, any guarantees, litigations or claims of material importance, pending or threatened against any member of our Group or other material contingent liabilities. After due and careful consideration, our Directors confirm that there had been no material adverse change in our indebtedness since October 31, 2022 and up to the Latest Practicable Date.

RELATED PARTY TRANSACTIONS

During the Track Record Period, we had carried out transactions with related parties as set forth in note 30 in the Accountants' Report in Appendix I to this document. Our related parties mainly consisted of LIG, Shandong Luye, Nanjing Luye and other entities controlled by Mr. Liu Dian Bo, director of Luye Pharma.

Our transactions with related parties primarily include (i) receipt of repayment and interest income from LIG attributable to loans that bear interest at rates of 4.35% to 6.18% per annum we made to LIG, (ii) transactions that are trade in nature, including primarily the purchase of materials, property, plant and equipment and the procurement of lease and property management services that we received from Shandong Luye and Nanjing Luye and (iii) non-trade interest-free and unsecured payments and advances repayable on demand we made to or received from them. We do not expect to enter into such borrowing arrangements with related parties after [**REDACTED**]. Our other transactions with related parties primarily include debt waivers exempting us from our payables to related parties and the guarantee of Bank of China Loan which will be released upon the [**REDACTED**].

Our Directors are of the view that each of the above transactions that are trade in nature (i) was determined on normal commercial terms, negotiated on arm's length basis and on similar basis as we conducted businesses with other independent third parties and (ii) and would not distort our track record results or make the historical results not reflective of our future performance. Our Directors also confirm that all related party balances which are non-trade in nature will be fully settled prior to the [**REDACTED**]. For further details on related party balances and transactions, please refer to note 30 in the Accountants' Report in Appendix I to this document.

CAPITAL EXPENDITURE

Our capital expenditure during the Track Record Period represented purchases of property, plant and equipment to enhance our research and development capabilities and expand our business operation. For the years ended December 31, 2020 and 2021, our additions to property, plant and equipment were RMB14.9 million and RMB90.3 million, respectively, and RMB84.2 million for the six months ended June 30, 2022.

We have financed our capital expenditure primarily through proceeds from the pre-[**REDACTED**] investments and bank borrowings. Going forward, we expect that our capital expenditure will continue to consist primarily of funds to ramp up our production in connection with the sales of Boyounuo® (BA1101), purchases of machinery and equipment for our offices and manufacturing facilities, as well as equipment for our R&D functions, as we continue to progress the development of our product candidates. We expect to finance such capital expenditure needs primarily with various channels, including the [**REDACTED**] from the [**REDACTED**], debt financing, and the operating cash flow generated from the commercial sales of Boyounuo® (BA1101).

COMMITMENTS

We have leased certain offices, equipment and buildings under operating lease arrangements ranging from one to five years in duration. As of June 30, 2022, there were no future minimum lease payments under short-term lease and leases not yet commenced to which we had committed.

We had capital commitments for the acquisition of property, plant and equipment with amounts of RMB13.3 million and RMB109.0 million as of December 31, 2020 and December 31, 2021, respectively, and RMB182.9 million as of June 30, 2022. They primarily relate to expenditures expected to be incurred for the purchase of machinery and renovation of our existing laboratories and buildings.

CONTINGENT LIABILITIES

We did not have any contingent liabilities during the Track Record Period and up to the Latest Practicable Date.

KEY FINANCIAL RATIOS

The table below sets forth, as of the dates indicated, certain of our key financial ratios:

	For the year ended/ As of December 31,		For the six months ended/As of June 30,
	2020	2021	2022
Gross margin[(1)]	N/A[(2)]	67.1%	66.7%
Current ratio[(3)]	23.2%	360.8%	243.3%
Quick ratio[(4)]	18.3%	322.9%	198.4%

Notes:

(1) Gross margin is calculated as gross profit divided by revenue, multiplied by 100%.

(2) We did not have gross margin in 2020, as we only started to generate revenue in 2021.

(3) Current ratio is calculated as current assets divided by current liabilities, multiplied by 100%.

(4) Quick ratio is calculated as current assets minus inventories then divided by current liabilities, multiplied by 100%.

Gross margin

Our gross margin increased from nil in 2020 to 67.1% in 2021, attributable to the sales of Boyounuo® (BA1101) that commenced in May 2021. Our gross margin slightly decreased from 67.1% in 2021 to 66.7% for the six months ended June 30, 2022, mainly attributable to the temporary closing of our production facilities leading to higher unit cost of manufacturing in February 2022 during the Chinese New Year holiday and for regular maintenance and repair as well as GMP certification work.

Current ratio

Our current ratio increased from 23.2% as of December 31, 2020 to 360.8% as of December 31, 2021, primarily due to (i) a significant increase in cash and cash equivalents partly as a result of capital contributions from shareholders and (ii) a decrease in other payables mainly due to the settlement of a related-party loan. Our current ratio decreased from 360.8% as of December 31, 2021 to 243.3% as of June 30, 2022, mainly attributable to (i) a significant decrease in cash and cash equivalents used in operating activities, increase in intangible assets mainly reflecting the capitalization of the research and development costs related to BA1102, BA9101 and BA6101 and purchases of property, plant and equipment mainly related to the new production lines and (ii) an increase in other payables and accruals mainly due to the increased accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) as well as accrued [**REDACTED**] expenses for the proposed [**REDACTED**].

Quick ratio

Our quick ratio increased from 18.3% as of December 31, 2020 to 322.9% as of December 31, 2021, primarily due to (i) a significant increase in cash and cash equivalents partly as a result of capital contributions from shareholders and (ii) a decrease in other payables mainly due to the settlement of a related-party loan. Our quick ratio decreased from 322.9% as of December 31, 2021 to 198.4% as of June 30, 2022, mainly attributable to (i) a significant decrease in cash and cash equivalents used in operating activities, increase in intangible assets mainly reflecting the capitalization of the research and development costs related to BA1102, BA9101 and BA6101 and purchases of property, plant and equipment mainly related to the new production lines, (ii) an increase in inventories as a result of our continued procurement of raw materials (a) for the production and sales of Boyounuo® (BA1101) and (b) to strategically mitigate the risks associated with supply chain disruption caused by the COVID-19 and (iii) an increase in other payables and accruals mainly due to the increased accrued promotion expenses mainly in connection with the sales of Boyounuo® (BA1101) as well as accrued [**REDACTED**] expenses for the proposed [**REDACTED**].

QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT FINANCIAL RISK

Our principal financial instruments comprise bank loans and cash and short term deposits. We also have various other financial assets and liabilities such as trade receivables and trade payables, which arise directly from our operations. The key financial risks include interest rate risk, foreign currency risk, credit risk and liquidity risk. Our overall risk management focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance. We set forth a summary of our approach to managing these types of risks. See note 33 to the Accountant's Report in Appendix I to this document for further details.

Interest rate risk

Our exposure to the risk of changes in market interest rates relates primarily to our interest-bearing bank loans with a floating interest rate. We mitigate the risk by monitoring closely the movements in interest rates and reviewing our banking facilities regularly. We have not used any interest rate swap to hedge our exposure to interest rate risk. See note 33 to the Accountant's Report in Appendix I to this document for further details.

Foreign currency risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. We have currency exposures mainly arising from cash at banks denominated in United State dollar. At present, we do not intend to seek to hedge our exposure to foreign exchange fluctuations. We constantly monitor the economic situation and our foreign exchange risk profile and will consider appropriate hedging measures in the future should the need arise. See note 33 to the Accountant's Report in Appendix I to this document for further details.

Credit risk

We trade only with recognized and creditworthy third parties. It is our policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and our exposure to bad debts is not significant.

Since we trade only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty, by geographical region. There are no significant concentrations of credit risk within our Group as the customer bases of our trade receivables are widely dispersed with different customers. See note 33 to the Accountant's Report in Appendix I to this document for further details.

Liquidity risk

We monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations of cash flows.

Our objective is to maintain a balance between continuity of funding and flexibility through the use of interest-bearing bank loans and lease liabilities. See note 33 to the Accountant's Report in Appendix I to this document for further details.

DIVIDENDS

We did not declare or pay any dividends during the Track Record Period and we do not have a fixed dividend payout ratio. The Board has absolute discretion as to whether to declare any dividend for any year and, if it decides to declare a dividend, how much to declare. The Board will submit such proposal in respect of dividend payments to the Shareholders' general meeting for approval. The amount of any dividends to be declared or paid will depend on, among other things, applicable laws and regulations, our results of operations, cash flows, financial condition and operating and capital requirements. Any future declaration of dividends may or may not reflect our prior declarations of dividends.

DISTRIBUTABLE RESERVES

As of June 30, 2022, we did not have any distributable reserves as we did not have positive retained profits.

[REDACTED] EXPENSES

[**REDACTED**] expenses represent professional fees, [**REDACTED**] and other fees incurred in connection with the [**REDACTED**]. We expect to incur total [**REDACTED**] of approximately HK$[**REDACTED**] (assuming the [**REDACTED**] is not exercised and based on the [**REDACTED**] of HK$[**REDACTED**] per [**REDACTED**], being the mid-point of the [**REDACTED**] range), of which approximately RMB[**REDACTED**] and RMB [**REDACTED**], respectively, has been charged to profit or loss in 2021 and for the six months ended June 30, 2022. The total [**REDACTED**] expenses consist of approximately HK$[**REDACTED**] [**REDACTED**] fees (including [**REDACTED**] and incentive fee, SFC transaction levy, Stock Exchange trading fee and AFRC transaction levy) and approximately HK$[**REDACTED**] non-[**REDACTED**] fees mainly including (i) fees and expenses of professional parties such as legal advisor(s), accountant(s) and other professional parties of approximately HK$[**REDACTED**] and (ii) other fees and expenses of approximately HK$[**REDACTED**]. Among the total [**REDACTED**] expenses, approximately HK$[**REDACTED**] is expected to be charged to profit or loss, and approximately HK$[**REDACTED**] directly attributable to the issue of the Shares is expected to be deducted from equity upon the completion of the [**REDACTED**]. Our total [**REDACTED**] expenses are estimated to account for [**REDACTED**]% of the gross [**REDACTED**] of the [**REDACTED**]. The [**REDACTED**] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

See "Unaudited Pro Forma Financial Information" in Appendix II to this document for further details of our unaudited pro forma statement of adjusted consolidated net tangible assets.

OFF-BALANCE SHEET ARRANGEMENTS

During the Track Record Period and as of the Latest Practicable Date, we had no off-balance sheet arrangements.

NO ADDITIONAL DISCLOSURE REQUIRED UNDER THE LISTING RULES

As of the Latest Practicable Date, we were not aware of any circumstances that would give rise to a disclosure requirement under Rules 13.13 to Rules 13.19 of the Listing Rules.

DIRECTORS' CONFIRMATION OF NO MATERIAL ADVERSE CHANGE

Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 in several parts of China, including some of our regional markets such as Shanghai, Guangdong Province, Shandong Province and Jilin Province, and various restrictive measures, such as lockdowns, quarantines, closure of work places, travel restrictions and home office policies have been implemented. As a result of the restrictive measures, our sales of Boyounuo® (BA1101) to some extent have been affected by patients' limited access to medical services in the affected regions.

However, the restrictive measures have not had any material impact on our regulatory and clinical trial plans of the Core Products and pipeline candidates, our production capability, our commercialization plans or our overall financial performance. We also believe our sales of Boyounuo® (BA1101) will resume its normal level after the lifting of various restrictive measures primarily because of its continuing strong demand in China.

Our Directors confirm that, having performed reasonable due diligence on our Group, there has been no material adverse change in our financial or trading position or prospects since December 31, 2021 and up to the date of this document.

Our Directors confirmed that the COVID-19 outbreak did not have any material adverse impact on our business operations and financial performance as of the Latest Practicable Date, primarily because: (i) there had been no material disruption of our ongoing clinical trials of our Core Products; (ii) we had not encountered any material supply chain disruption; and (iii) there had been no material disruption of our sales and marketing activities. We cannot foresee when the COVID-19 outbreak will become completely under control or whether COVID-19 will have a material and adverse impact on our business going forward. See "Risk Factors — Risks relating to our operations — Our business and operations could be adversely affected by the effects of health pandemics or epidemics, including the outbreak of COVID-19, in regions where we, or third parties on which we rely, have significant manufacturing facilities, concentrations of clinical trial sites or other business operations" for further details.

FUTURE PLANS

See "Business — Our strategies" for a detailed description of our future plans and strategies.

[REDACTED]

We estimate that we will receive [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**], after deducting [**REDACTED**], fees and estimated expenses payable by us in connection with the [**REDACTED**], and assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] range stated in this document, and without taking into account the [**REDACTED**]. If the [**REDACTED**] is set at HK$[**REDACTED**] per Share, being the high end of the indicative [**REDACTED**] range, the [**REDACTED**] from the [**REDACTED**] will increase by approximately HK$[**REDACTED**]. If the [**REDACTED**] is set at HK$[**REDACTED**] per Share, being the low end of the indicative [**REDACTED**] range, the [**REDACTED**] from the [**REDACTED**] will decrease by approximately HK$[**REDACTED**].

Assuming an [**REDACTED**] at the mid-point of the indicative [**REDACTED**] range, we currently intend to apply these [**REDACTED**] for the following purposes:

- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for the research and development of our Core Products.

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1102, of which (i) approximately [**REDACTED**]% is for preparatory works leading to registration in China, including approximately [**REDACTED**]% for pharmacy and clinical site verification, approximately [**REDACTED**]% for production site inspection and approximately [**REDACTED**]% for regulatory submission costs in China; and (ii) approximately [**REDACTED**]% is for the overseas clinical development and registrations, including approximately [**REDACTED**]% for the Phase 3 clinical trial costs in the EU and approximately [**REDACTED**]% for the clinical registration-related costs in the EU and the United States. Because BA1102 is under clinical trial by virtue of the clinical trial of BA6101 in the EU, certain of BA6101's clinical trial expenses in the EU will be apportioned to the R&D costs of BA1102. Within the [**REDACTED**] to be used for BA1102, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals.

As of the Latest Practicable Date, BA1102 was under Phase 3 clinical trial in China and under Phase 1 clinical trial in the EU (by virtue of the clinical trial of BA6101 in the EU because they contain the same active agent, denosumab, and have the same mechanism of action), and we expect to submit its BLA in the first quarter of 2023 in China. See "Business — Our biosimilar portfolio — Our Core Product: BA1102 denosumab injection (a biosimilar to Xgeva®)" for more details;

– Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA6101 for the overseas clinical development and registrations, including approximately [**REDACTED**]% for the Phase 3 clinical trial costs in the EU and approximately [**REDACTED**]% for the clinical registration-related costs in the EU and the United States. Within the [**REDACTED**] to be used for BA6101, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals.

  We received the regulatory approval to commence commercialization of BA6101 in November 2022 in China. As of the Latest Practicable Date, it was currently under Phase 1 clinical trial in the EU. See "Business — Our biosimilar portfolio — Our Core Product: BA6101 denosumab injection (a biosimilar to Prolia®)" for more details; and

– Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for LY-CovMab for its Phase 2 clinical trial costs. Within the [**REDACTED**] to be used for LY-CovMab, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals.

  As of the Latest Practicable Date, LY-CovMab was in Phase 2 clinical trial in China. See "Business — Our innovative antibody portfolio — Our Core Product: LY-CovMab" for more details.

- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for the research and development of other products in our pipeline. We estimate that such allocation of [**REDACTED**] cannot fully support the development of each product candidate to commercialization, and we plan to source funding from own funds and bank loans.

  – Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for our biosimilar candidates of BA9101, BA1104 and BA5101:

    - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA9101 for process characterization and process validation. As of the Latest Practicable Date, BA9101 was under Phase 3 clinical trial in China, and we expect to submit its BLA in the first half of 2024 in China. See "Business — Our biosimilar portfolio — BA9101 aflibercept intraocular injection (a biosimilar to Eylea®)" for more details;

    - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1104 for the Phase 1 clinical trial. Within the [**REDACTED**] to be used for BA1104, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. We obtained the IND approval from the CDE in April 2021 and initiated the Phase 1 clinical trial in China in September 2022 for BA1104. See "Business — Our biosimilar portfolio — BA1104 (a biosimilar to Opdivo®)" for more details;

    - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA5101 for the Phase 3 clinical trial. Within the [**REDACTED**] to be used for BA5101, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. As of the Latest Practicable Date, we were conducting the BA5101's Phase 3 clinical trial and we expect to submit its BLA in the first half of 2024 in China. See "Business — Our biosimilar portfolio — BA5101 (a biosimilar to Trulicity®)" and "Summary — Recent Development — Milestones achieved on Commercialized Product and other product candidates" for more details;

- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for our innovative antibody candidates of BA1105, BA1201, BA-CovMab, BA1106, BA1202, BA1301 and BA2101:

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1105 for the Phase 1 clinical trial. Within the [**REDACTED**] to be used for BA1105, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. As of the Latest Practicable Date, we were conducting Phase 1 clinical trial in China for BA1105. See "Business — Our innovative antibody portfolio — BA1105" for more details;

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1201 for the Phase 1 clinical trial. Within the [**REDACTED**] to be used for BA1201, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. As of the Latest Practicable Date, we were conducting the Phase 1 clinical trial of BA1201 in China. See "Business — Our innovative antibody portfolio — BA1201" for more details;

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA- CovMab for its Phase 1 clinical trial in China. Within the [**REDACTED**] to be used for BA-CovMab, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. In September 2022, we received the IND approval for BA-CovMab. We have been conducting the Phase 1 clinical trial in China since October 2022. See "Business — Our innovative antibody portfolio — BA-CovMab" for more details;

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1106 for its Phase 1 clinical trial. Within the [**REDACTED**] to be used for BA1106, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. As of the Latest Practicable Date, we were preparing for the Phase 1 clinical trial of BA1106 in China. See "Business — Our innovative antibody portfolio — Other innovative antibody candidates" for more details;

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1202 for its Phase 1 clinical trial. Within the [**REDACTED**] to be used for BA1202, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. As of the Latest Practicable Date, we were conducting the pre-clinical process research of BA1202. See "Business — Our innovative antibody portfolio — Other innovative antibody candidates" for more details;

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA1301 for its Phase 1 clinical trial. Within the [**REDACTED**] to be used for BA1301, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. We submitted the IND application for BA1301 in October 2022. See "Business — Our innovative antibody portfolio — Other innovative antibody candidates" for more details; and

  - Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for BA2101 for its Phase 1 clinical trial in China. Within the [**REDACTED**] to be used for BA2101, we will spend approximately [**REDACTED**]% for engaging CROs, CDMOs and hospitals. In October 2022, we received the IND approval for BA2101. We plan to initiate the Phase 1 clinical trial in China in the first quarter of 2023. See "Business — Our innovative antibody portfolio — Other innovative antibody candidates" for more details.

- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for commercialization purposes. We intend to focus our commercialization efforts on Boyounuo® (BA1101), our Core Products and other products for which approvals are expected in the coming years, namely BA1102, BA6101, BA9101 and BA5101. We plan to establish an experienced and professional sales and marketing team, which will mainly focus on market access, medical affairs, and academic promotion in the oncology field. We expect to have a 100-person sales and marketing team responsible for the nationwide marketing and sales of our pipeline products in their scheduled rollouts. We expect to expand our sales and marketing team to 60 persons by the end of 2022 and further expend to 100 person by the end of 2023. Our sales and marketing team will manage the marketing network spanning Beijing, Shanghai, Guangzhou, and other regions and continue to strengthen the collaboration with various resourceful business partners including distributors and promoters. Our sales and marketing team will continue to focus on municipalities and certain prefecture-level cities in provinces and autonomous regions in China while other third-party promoters focus on counties of provinces and autonomous regions in China. Our sales and marketing team will be responsible for data analysis, marketing strategy formulation, academic promotion activities, customer relationship management and effective market coverage and

penetration. The third-party promoters will maintain a consistent marketing strategy with our sales and marketing team, and conduct collaborative promotion activities. Third-party distributors will still be our direct customers who sell and deliver our products to hospitals.

- Approximately [**REDACTED**]%, or HK$[**REDACTED**], will be used for working capital and other general corporate purposes.

The above allocation of the [**REDACTED**] from the [**REDACTED**] will be adjusted on a pro rata basis in the event that the [**REDACTED**] is fixed at a higher or lower level compared to the mid-point of the indicative [**REDACTED**] range stated in this document.

If the [**REDACTED**] is exercised in full, the [**REDACTED**] that we will receive will be approximately HK$[**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] per Share (being the mid-point of the indicative [**REDACTED**] range). In the event that the [**REDACTED**] is exercised in full, we intend to apply the additional [**REDACTED**] to the above purposes in the proportions stated above.

To the extent that the [**REDACTED**] from the [**REDACTED**] are not immediately used for the purposes described above and to the extent permitted by the relevant laws and regulations, they will be placed in short-term demand deposits with authorized and licensed commercial banks or financial institutions.

We will issue an appropriate announcement if there is any material change to the above proposed [**REDACTED**].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

INDEPENDENCE OF THE JOINT SPONSORS

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

[REDACTED]

[REDACTED]

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[REDACTED]

The following is the text of a report received from our Company's reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.

[To insert the firm's letterhead]

ACCOUNTANTS' REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF SHANDONG BOAN BIOTECHNOLOGY CO., LTD. AND UBS SECURITIES HONG KONG LIMITED AND ESSENCE CORPORATE FINANCE (HONG KONG) LIMITED

Introduction

We report on the historical financial information of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") and its subsidiaries (together, the "**Group**") set out on pages I-5 to I-83, which comprises the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for the years ended 31 December 2020 and 2021, and the six months ended 30 June 2022 (the "**Relevant Periods**"), and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2020 and 2021 and 30 June 2022 and a summary of significant accounting policies and other explanatory information (together, the "**Historical Financial Information**"). The Historical Financial Information set out on pages I-5 to I-83 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the "**Document**") in connection with the [**REDACTED**] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**").

Directors' responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants' responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants' Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants' judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity's preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants' report, a true and fair view of the financial position of the Group and the Company as at 31 December 2020 and 2021 and 30 June 2022 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Review of interim comparative financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the six months ended 30 June 2021 and other explanatory information (the "**Interim Comparative Financial Information**"). The directors of the Company are responsible for the preparation of the Interim Comparative Financial Information in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants' report, is not prepared, in all material respects, in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

[●]
Certified Public Accountants
Hong Kong
[Date]

I. HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants' report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants (the "**Underlying Financial Statements**").

The Historical Financial Information is presented in Renminbi ("**RMB**") and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended 31 December		Six months ended 30 June	
		2020	2021	2021	2022
	Notes	*RMB'000*	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
REVENUE	*5*	–	158,704	12,094	220,690
Cost of sales		–	(52,190)	(3,311)	(73,421)
Gross profit		–	106,514	8,783	147,269
Other income and gains	*5*	12,073	13,365	5,745	13,508
Research and development costs		(236,317)	(231,567)	(111,558)	(169,057)
Administrative expenses		(4,464)	(42,165)	(18,220)	(37,563)
Selling and distribution expenses		–	(54,048)	(5,874)	(100,827)
Other expenses		(11)	(5,917)	(1,228)	(3)
Finance costs	*7*	(11,819)	(11,599)	(5,575)	(6,622)
LOSS BEFORE TAX	*6*	(240,538)	(225,417)	(127,927)	(153,295)
Income tax expense	*10*	–	–	–	–
LOSS FOR THE YEAR/PERIOD		(240,538)	(225,417)	(127,927)	(153,295)
Attributable to:					
Owners of the parent		(240,538)	(225,417)	(127,927)	(153,295)
OTHER COMPREHENSIVE LOSS					
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of foreign operations		–	(128)	14	1,077
OTHER COMPREHENSIVE LOSS FOR THE YEAR/PERIOD, NET OF TAX		–	(128)	14	1,077
TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD		(240,538)	(225,545)	(127,913)	(152,218)
Attributable to:					
Owners of the parent		(240,538)	(225,545)	(127,913)	(152,218)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT					
Basic and diluted (RMB)	*12*	(6.13)	(0.47)	(0.28)	(0.31)

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		As at 31 December		As at 30 June
		2020	2021	2022
	Notes	*RMB'000*	*RMB'000*	*RMB'000*
NON-CURRENT ASSETS				
Property, plant and equipment	*13*	462,170	504,842	562,650
Advance payments for property, plant and equipment		11,626	79,192	33,363
Right-of-use assets	*14(a)*	16,906	16,718	13,705
Intangible assets	*15*	325,266	566,002	653,210
Total non-current assets		815,968	1,166,754	1,262,928
CURRENT ASSETS				
Inventories	*16*	19,672	98,840	140,877
Trade and notes receivables	*17*	700	107,267	139,030
Prepayments, other receivables and other assets	*18*	68,061	75,328	68,112
Pledged deposits	*19*	–	44,853	2,188
Time deposits over three months	*19*	–	81,859	100,000
Cash and cash equivalents	*19*	3,629	531,703	312,241
Total current assets		92,062	939,850	762,448
CURRENT LIABILITIES				
Lease liabilities	*14(b)*	7,647	10,019	9,980
Trade and notes payables	*20*	91,585	138,714	120,539
Other payables and accruals	*21*	12,187	79,024	151,318
Interest-bearing bank loans	*22*	–	10,000	26,680
Due to related parties	*30(c)*	284,758	22,725	4,824
Total current liabilities		396,177	260,482	313,341
NET CURRENT ASSETS/(LIABILITIES)		(304,115)	679,368	449,107
TOTAL ASSETS LESS CURRENT LIABILITIES		511,853	1,846,122	1,712,035

	Notes	As at 31 December 2020 RMB'000	2021 RMB'000	As at 30 June 2022 RMB'000
TOTAL ASSETS LESS CURRENT LIABILITIES		511,853	1,846,122	1,712,035
NON-CURRENT LIABILITIES				
Lease liabilities	*14(b)*	8,486	4,504	1,323
Interest-bearing bank loans	*22*	–	240,000	225,000
Government grants	*23*	2,800	1,800	–
Other non-current liabilities	*24*	18,978	48,131	77,162
Total non-current liabilities		30,264	294,435	303,485
Net assets		481,589	1,551,687	1,408,550
EQUITY				
Equity attributable to owners of the parent				
Share capital	*25*	–	498,583	498,583
Paid-in capital	*25*	360,000	–	–
Reserves	*26*	121,589	1,053,104	909,967
Total equity		481,589	1,551,687	1,408,550

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2020

	Share capital *RMB'000 (note 25)*	Paid-in capital *RMB'000 (note 25)*	Share premium* *RMB'000 (note 26)*	Other reserves* *RMB'000 (note 26)*	Safety production reserve* *RMB'000 (note 26)*	Exchange fluctuation reserve* *RMB'000 (note 26)*	Accumulated losses* *RMB'000*	Total equity *RMB'000*
At 1 January 2020	–	10,000	–	–	–	–	(439,057)	(429,057)
Loss and total comprehensive loss for the year	–	–	–	–	–	–	(240,538)	(240,538)
Capital contribution from a shareholder	–	350,000	–	799,654	–	–	–	1,149,654
Exemption of payables to a former shareholder	–	–	–	1,530	–	–	–	1,530
At 31 December 2020	–	360,000	–	801,184	–	–	(679,595)	481,589

Year ended 31 December 2021

	Share capital *RMB'000 (note 25)*	Paid-in capital *RMB'000 (note 25)*	Share premium* *RMB'000 (note 26)*	Other reserves* *RMB'000 (note 26)*	Safety production reserve* *RMB'000 (note 26)*	Exchange fluctuation reserve* *RMB'000 (note 26)*	Accumulated losses* *RMB'000*	Total equity *RMB'000*
At 1 January 2021	–	360,000	–	801,184	–	–	(679,595)	481,589
Loss for the year	–	–	–	–	–	–	(225,417)	(225,417)
Exchange differences on translation of foreign operations	–	–	–	–	–	(128)	–	(128)
Total comprehensive loss for the year	–	–	–	–	–	(128)	(225,417)	(225,545)
Capital contribution from shareholders before conversion into a joint stock company	–	123,199	–	896,099	–	–	–	1,019,298
Conversion into a joint stock company	484,000	(483,199)	965,556	(1,697,283)	–	–	730,926	–
Capital contribution from shareholders after conversion into a joint stock company	14,583	–	196,332	–	–	–	–	210,915
Exemption of payables to a shareholder	–	–	–	44,155	–	–	–	44,155
Appropriation to safety production reserve	–	–	–	–	2,507	–	(2,507)	–
Safety production reserve used	–	–	–	–	(491)	–	491	–
Share based payment arrangements *(note 27)*	–	–	–	21,275	–	–	–	21,275
At 31 December 2021	498,583	–	1,161,888	65,430	2,016	(128)	(176,102)	1,551,687

Six months ended 30 June 2022

	Share capital *RMB'000 (note 25)*	Paid-in capital *RMB'000 (note 25)*	Share premium* *RMB'000 (note 26)*	Other reserves* *RMB'000 (note 26)*	Safety production reserve* *RMB'000 (note 26)*	Exchange fluctuation reserve* *RMB'000 (note 26)*	Accumulated losses* *RMB'000*	Total equity *RMB'000*
At 1 January 2022	498,583	–	1,161,888	65,430	2,016	(128)	(176,102)	1,551,687
Loss for the period	–	–	–	–	–	–	(153,295)	(153,295)
Exchange differences on translation of foreign operations	–	–	–	–	–	1,077	–	1,077
Total comprehensive loss for the period	–	–	–	–	–	1,077	(153,295)	(152,218)
Appropriation to safety production reserve	–	–	–	–	3,003	–	(3,003)	–
Safety production reserve used	–	–	–	–	(863)	–	863	–
Share-based payment arrangements *(note 27)*	–	–	–	9,081	–	–	–	9,081
At 30 June 2022	498,583	–	1,161,888	74,511	4,156	949	(331,537)	1,408,550

* These reserve accounts comprise the consolidated reserves of RMB121,589,000, RMB1,053,104,000 and RMB909,967,000 in the consolidated statements of financial position as at 31 December 2020 and 2021 and 30 June 2022, respectively.

Six months ended 30 June 2021 (unaudited)

	Share capital *RMB'000 (note 25)*	Paid-in capital *RMB'000 (note 25)*	Share premium *RMB'000 (note 26)*	Other reserves *RMB'000 (note 26)*	Safety production reserve *RMB'000 (note 26)*	Exchange fluctuation reserve *RMB'000 (note 26)*	Accumulated losses *RMB'000*	Total equity *RMB'000*
At 1 January 2021	–	360,000	–	801,184	–	–	(679,595)	481,589
Loss for the period (unaudited)	–	–	–	–	–	–	(127,927)	(127,927)
Exchange differences on translation of foreign operations (unaudited)	–	–	–	–	–	14	–	14
Total comprehensive loss for the period (unaudited)	–	–	–	–	–	14	(127,927)	(127,913)
Capital contribution from shareholders before conversion into a joint stock company	–	123,199	–	896,099	–	–	–	1,019,298
Conversion into a joint stock company	484,000	(483,199)	965,556	(1,697,283)	–	–	730,926	–
Appropriation to safety production reserve (unaudited)	–	–	–	–	442	–	(442)	–
Safety production reserve used (unaudited)	–	–	–	–	(163)	–	163	–
Share-based payment arrangements (unaudited)	–	–	–	7,064	–	–	–	7,064
At 30 June 2021 (unaudited)	484,000	–	965,556	7,064	279	14	(76,875)	1,380,038

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended 31 December 2020 RMB'000	2021 RMB'000	Six months ended 30 June 2021 RMB'000 (Unaudited)	2022 RMB'000
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(240,538)	(225,417)	(127,927)	(153,295)
Adjustments for:					
Finance costs	7	11,819	11,599	5,575	6,622
Bank interest income	5	(31)	(9,101)	(4,418)	(3,889)
Interest income from a related party	5	(1,164)	–	–	–
Loss on disposal of items of property, plant and equipment	6	11	66	65	3
Depreciation of property, plant and equipment	6	10,480	30,895	11,426	23,260
Depreciation of right-of-use assets	6	2,779	8,080	3,290	4,667
Amortisation of intangible assets	6	2,623	11,034	3,026	8,181
Impairment of trade receivables	17	–	–	–	26
Share-based payment expense	27	–	21,275	7,064	9,081
Foreign exchange difference, net		–	4,949	487	(2,717)
		(214,021)	(146,620)	(101,412)	(108,061)
Increase in inventories		(17,116)	(79,168)	(30,017)	(42,037)
Decrease/(increase) in trade and notes receivables		5,000	(106,567)	(10,597)	(31,789)
Decrease/(increase) in prepayments, other receivables and other assets		(22,932)	(6,697)	(4,884)	10,278
Decrease/(increase) in pledged deposits		–	(26,712)	(36,377)	24,524
Increase/(decrease) in trade and notes payables		52,442	47,129	17,621	(18,175)
Increase/(decrease) in other payables and accruals		(3,316)	64,222	9,441	70,749
Increase/(decrease) in government grants		1,600	(1,000)	–	(1,800)
Decrease in amounts due to related parties		(327,355)	(20,018)	(14,066)	(17,901)
Increase in other non-current liabilities		18,978	29,153	18,600	–
Cash used in operations		(506,720)	(246,278)	(151,691)	(114,212)
Net cash flows used in operating activities		(506,720)	(246,278)	(151,691)	(114,212)

	Note	Year ended 31 December 2020 RMB'000	Year ended 31 December 2021 RMB'000	Six months ended 30 June 2021 RMB'000 (Unaudited)	Six months ended 30 June 2022 RMB'000
CASH FLOWS FROM INVESTING ACTIVITIES					
Purchases of items of property, plant and equipment		(25,053)	(107,729)	(63,658)	(39,116)
Increase in intangible assets		(106,223)	(233,516)	(100,608)	(62,524)
Increase in time deposits over three months		–	(100,000)	(100,000)	–
Receipt of repayment from a related party		112,458	–	–	–
Bank interest received		31	8,949	4,043	4,036
Net cash flows used in investing activities		(18,787)	(432,296)	(260,223)	(97,604)
CASH FLOWS FROM FINANCING ACTIVITIES					
New bank loans		–	–	–	6,680
Repayment of bank loans		(485,933)	–	–	(5,000)
Capital contribution from shareholders		798,270	1,230,213	1,019,298	–
Advances from a related party		886,082	2,830	2,830	–
Repayment of advances from a related party		(659,078)	–	–	–
Principal portion of lease payments		(289)	(9,426)	(491)	(5,583)
Interest paid		(11,819)	(11,599)	(5,281)	(6,622)
Payment for deferred **[REDACTED]** expenses		**[REDACTED]**	**[REDACTED]**	**[REDACTED]**	**[REDACTED]**
Net cash flows from/(used in) financing activities		527,233	1,211,729	1,016,220	(11,462)

	Note	Year ended 31 December 2020 RMB'000	2021 RMB'000	Six months ended 30 June 2021 RMB'000 (Unaudited)	2022 RMB'000
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		1,726	533,155	604,306	(223,278)
Cash and cash equivalents at beginning of year/period		1,903	3,629	3,629	531,703
Effect of foreign exchange rate changes, net		–	(5,081)	(462)	3,816
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD	*19*	3,629	531,703	607,473	312,241
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and bank balances	*19*	3,629	558,415	643,850	314,429
Less: Pledged deposits for notes payable		–	(26,712)	(36,377)	(2,188)
Cash and cash equivalents as stated in the consolidated statements of financial position and the consolidated statements of cash flows	*19*	3,629	531,703	607,473	312,241

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	Notes	As at 31 December 2020 RMB'000	2021 RMB'000	As at 30 June 2022 RMB'000
NON-CURRENT ASSETS				
Property, plant and equipment	*13*	462,170	487,604	546,410
Advance payments for property, plant and equipment		11,329	79,192	33,363
Right-of-use assets	*14(a)*	15,046	12,437	12,423
Intangible assets	*15*	325,266	566,002	653,210
Investments in subsidiaries		2,000	34,480	53,656
Total non-current assets		815,811	1,179,715	1,299,062
CURRENT ASSETS				
Inventories	*16*	19,672	98,840	140,877
Trade and notes receivables	*17*	700	107,267	139,030
Prepayments, other receivables and other assets	*18*	66,589	71,014	62,813
Due from a subsidiary	*30(c)*	3,800	34,904	42,337
Pledged deposits	*19*	–	44,853	2,188
Time deposits over three months	*19*	–	81,859	100,000
Cash and cash equivalents	*19*	1,915	503,016	298,913
Total current assets		92,676	941,753	786,158
CURRENT LIABILITIES				
Lease liabilities	*14(b)*	6,233	4,297	8,467
Trade and notes payables	*20*	90,368	137,677	120,084
Other payables and accruals	*21*	11,431	75,384	149,271
Interest-bearing bank loans	*22*	–	10,000	26,680
Due to a subsidiary	*30(c)*	–	–	4,195
Due to related parties	*30(c)*	284,758	2,600	4,278
Total current liabilities		392,790	229,958	312,975
NET CURRENT ASSETS/(LIABILITIES)		(300,114)	711,795	473,183
TOTAL ASSETS LESS CURRENT LIABILITIES		515,697	1,891,510	1,772,245

	Notes	As at 31 December 2020 RMB'000	2021 RMB'000	As at 30 June 2022 RMB'000
TOTAL ASSETS LESS CURRENT LIABILITIES		515,697	1,891,510	1,772,245
NON-CURRENT LIABILITIES				
Lease liabilities	*14(b)*	7,778	4,504	1,190
Interest-bearing bank loans	*22*	–	240,000	225,000
Government grants	*23*	2,800	1,800	–
Other non-current liabilities	*24*	18,978	48,131	77,162
Total non-current liabilities		29,556	294,435	303,352
Net assets		486,141	1,597,075	1,468,893
EQUITY				
Equity attributable to owners of the parent				
Share capital	*25*	–	498,583	498,583
Paid-in capital	*25*	360,000	–	–
Reserves	*26*	126,141	1,098,492	970,310
Total equity		486,141	1,597,075	1,468,893

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

The Company is a joint stock company with limited liability established in the People's Republic of China ("**PRC**"). The registered office of the Company is located at No. 39 Keji Avenue, High-Tech Industrial Development Zone, Yantai, Shandong Province, China.

During the Relevant Periods, the Company and its subsidiaries were principally engaged in the development, manufacture and commercialisation of high quality biologics in China and worldwide.

As at the end of the Relevant Periods, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies, the particulars of which are set out below:

Name	Place and date of incorporation/ registration and place of operations	Nominal value of issued ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
Nanjing Boan Biotechnology Co., Ltd.* ("**Boan Nanjing**") (南京博安生物技術有限公司) *(Note (a))*	PRC/Mainland China 15 July 2020	RMB2,000,000	100%	–	Early stage research and development in new antibody drugs
Boan Singapore Innovation Center Pte. Ltd. *(Note (b))*	Singapore 20 October 2020	US$8,000,000	100%	–	Overseas market development
Boan Boston LLC *(Note (c))*	United States of America ("**USA**") 20 October 2020	US$1	–	100%	Early stage research and development in new antibody drugs

Notes:

(a) The entity is a limited liability enterprise established under PRC law. No audited financial statements have been prepared for the year ended 31 December 2020 as it is not required by the local government to prepare statutory accounts. The statutory financial statements of Boan Nanjing for the year ended 31 December 2021 prepared under PRC Generally Accepted Accounting Principles ("**PRC GAAP**") were audited by Nanjing Nanshen Xidi Certified Public Accountants Co., Ltd. (南京南審希地會計師事務所有限公司), certified public accountants registered in the PRC.

(b) No audited financial statements have been prepared for this entity for the year ended 31 December 2020 as it had no operation in 2020. The statutory financial statements of Boan Singapore for the period from 20 October 2020 (date of corporation) to 31 December 2021 prepared under Financial Reporting Standards in Singapore ("**FRSs**") were audited by Ernst & Young LLP, public accountants and chartered accountants registered in Singapore.

(c) No audited financial statements have been prepared for this entity since the date of incorporation as it is not subject to any statutory audit requirement under the relevant rules and regulations in the jurisdiction of incorporation.

* The English name of this entity registered in the PRC represents the best efforts made by the management of the Company to directly translate its Chinese name as it did not register any official English name.

2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards ("**IFRSs**"), which comprise all standards and interpretations approved by the International Accounting Standards Board ("**IASB**"). All IFRSs effective for the accounting period commencing from 1 January 2022, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods.

The Historical Financial Information has been prepared under the historical cost convention, except for notes receivable which has been measured at fair value.

Basis of consolidation

The Historical Financial Information includes the financial information of the Company and its subsidiaries (collectively referred to as the "**Group**") for the Relevant Periods. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

(a) the contractual arrangement with the other vote holders of the investee;

(b) rights arising from other contractual arrangements; and

(c) the Group's voting rights and potential voting rights.

The financial information of the subsidiaries is prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Company and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group's share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.2 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[2]
IFRS 17	*Insurance Contracts*[1]
Amendments to IFRS 17	*Insurance Contracts*[1, 3]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[1]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[1]
Amendments to IAS 8	*Definition of Accounting Estimates*[1]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[1]
Amendment to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 — Comparative Information*[1]

[1] Effective for annual periods beginning on or after 1 January 2023

[2] No mandatory effective date yet determined but available for adoption

[3] As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group considers that these new and revised IFRSs may result in changes in accounting policies but are unlikely to have a significant impact on the Group's financial performance and financial position.

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures equity investments and wealth management products investments at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 — based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the Historical Financial Information on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories, deferred tax assets and financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs. In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises, unless the asset is carried at a revalued amount, in which case the reversal of the impairment loss is accounted for in accordance with the relevant accounting policy for that revalued asset.

Related parties

A party is considered to be related to the Group if:

(a) the party is a person or a close member of that person's family and that person

(i) has control or joint control over the Group;

(ii) has significant influence over the Group; or

(iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

(b) the party is an entity where any of the following conditions applies:

(i) the entity and the Group are members of the same group;

(ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);

(iii) the entity and the Group are joint ventures of the same third party;

(iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;

(v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;

(vi) the entity is controlled or jointly controlled by a person identified in (a);

(vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and

(viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The estimated useful lives of property, plant and equipment are as follows:

Buildings	20 to 40 years
Machinery and equipment	5 to 10 years
Office equipment	3 to 5 years

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents buildings under construction, and machinery and equipment under installation, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction and capitalised borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Technology know-how

Purchased technology know-how is stated at cost less any impairment losses and is amortised on the straight-line basis over its estimated useful life of 10 years, which is determined by the expected usage period after considering the technical obsolescence and estimates of useful lives of similar assets.

Software

Purchased software is stated at cost less any impairment losses and is amortised on the straight-line basis over its estimated useful life of 9 years, which is determined by the expected usage period after considering the technical obsolescence and estimates of useful lives of similar assets.

Research and development costs

All research costs are charged to profit or loss as incurred.

The expenditures on an internal research and development project are classified into expenditures in the research phase and expenditures in the development phase based on their nature and whether there is material uncertainty that the research and development activities can form an intangible asset at end of the project.

Expenditure in the development phase is capitalised and deferred if, and only if, all of the following have been demonstrated: (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale; (ii) the intention to complete the intangible asset and use or sell it; (iii) the ability to use or sell the intangible asset; (iv) how the intangible asset will generate probable future economic benefits; (v) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and (vi) its ability to measure reliably the expenditure attributable to the intangible asset during its development. Product development expenditure which does not meet these criteria is expensed when incurred.

The specific criteria for the capitalisation of development costs are as follows:

As for biosimilar products, expenditures incurred after the commencement of Phase III clinical trial for the medicines are capitalised and recognised as assets when the above six criteria are met.

As for innovative products, expenditures incurred after obtaining the new drug application approval from the drug regulatory organisation are capitalised and recognised as assets when the above six criteria are met.

Deferred development costs are stated at cost less any impairment losses and are amortised using the straight-line basis over the commercial lives of the underlying products not exceeding twenty years, commencing from the date when the regulatory and marketing approval is received, which is determined based on the management's expectation of the period over which the deferred development assets are expected to be available for use by the Group, by considering product life cycles for the asset, the estimates of useful lives of similar products and the market condition.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Leasehold land	38 years
Laboratory and office premises	1.5 to 5 years
Machinery and equipment	1.5 to 5 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment and buildings (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). Lease payments on short-term leases are recognised as an expense on a straight-line basis over the lease term.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value, plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for "Revenue recognition" below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest ("**SPPI**") on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through other comprehensive income (debt instruments)

For debt investments at fair value through other comprehensive income, interest income, foreign exchange revaluation and impairment losses or reversals are recognised in profit or loss and computed in the same manner as for financial assets measured at amortised cost. The remaining fair value changes are recognised in other comprehensive income. Upon derecognition, the cumulative fair value change recognised in other comprehensive income is recycled to profit or loss.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a "pass-through" arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group's continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses ("**ECLs**") for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

For debt investments at fair value through other comprehensive income, the Group applies the low credit risk simplification. At each reporting date, the Group evaluates whether the debt investments are considered to have low credit risk using all reasonable and supportable information that is available without undue cost or effort. In making that evaluation, the Group reassesses the external credit ratings of the debt investments. In addition, the Group considers that there has been a significant increase in credit risk when contractual payments are more than six months past due.

The Group considers a financial asset in default when contractual payments are six months past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Debt investments at fair value through other comprehensive income and financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables which apply the simplified approach as detailed below.

Stage 1 — Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs

Stage 2 — Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs

Stage 3 — Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on market historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, or payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and notes payables, other payables and accruals and interest-bearing bank loans.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (loans and payables)

After initial recognition, trade and notes payables, other payables and accruals and interest-bearing loans and borrowings are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average basis and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on temporary differences at the end of each reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- where the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and

- in respect of taxable temporary differences associated with investments in subsidiaries and an associate, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and

- in respect of deductible temporary differences associated with investments in subsidiaries and an associate, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each reporting period.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sale of products

Revenue from the sale of products is recognised at the point in time when control of the asset is transferred to the customer, generally on acceptance of the products.

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Contract liabilities

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods or services. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

Share-based payments

The Company operates a share-based payment scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group's operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments ("**equity-settled transactions**").

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using the back-solve method and equity value allocation based on the option pricing model, further details of which are given in note 27 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Other employee benefits

Pension schemes

Contributions made to the government retirement benefit fund under defined contribution retirement plans are charged to profit or loss as incurred. The Group participates in the national pension schemes as defined by the laws of the countries in which it has operations.

The employees of the Group's subsidiaries which operate in Mainland China are required to participate in central pension schemes operated by the local municipal government and the central government, respectively. These subsidiaries are required to contribute a certain percentage of payroll costs to the central pension schemes. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension schemes.

Borrowing costs

All borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

Dividends

Final dividends are recognised as a liability when they are approved by the shareholders in a general meeting.

Foreign currencies

The Historical Financial Information is presented in RMB, which is the Company's functional and presentation currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currencies of certain overseas subsidiaries are currencies other than RMB. As at the end of the reporting period, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions. The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in profit or loss.

For the purpose of the consolidated statement of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into RMB at the weighted average exchange rates for the year.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group's Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the Historical Financial Information:

Research and development costs

All research costs are charged to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalised and deferred in accordance with the accounting policy for research and development costs in note 2.3 to the Historical Financial Information. Determining the amounts to be capitalised requires management to make assumptions and judgements regarding to technical feasibility of completing the intangible asset, future economic benefits and so forth.

Significant judgement in determining the lease term of contracts with renewal options

The Group has several lease contracts that include extension and termination options. The Group applies judgement in evaluating whether or not to exercise the option to renew or terminate the lease. That is, it considers all relevant factors that create an economic incentive for it to exercise either the renewal or termination. After the commencement date, the Group reassesses the lease term if there is a significant event or change in circumstances that is within its control and affects its ability to exercise or not to exercise the option to renew or to terminate the lease (e.g., construction of significant leasehold improvements or significant customisation to the leased asset).

The Group includes the renewal period as part of the lease term for leases of laboratory and machinery and equipment due to the significance of these assets to its operations. These leases have a short non-cancellable period (i.e., one and a half to five years) and there will be a significant negative effect on production if a replacement is not readily available.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Leases - Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate ("IBR") to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group "would have to pay", which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary's functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary's stand-alone credit rating).

Impairment of non-financial assets

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of the reporting period. Indefinite life intangible assets are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Deferred tax assets

Deferred tax assets are recognised for unused tax losses and deductible temporary differences to the extent that it is probable that taxable profits will be available against which the losses and temporary differences can be utilised. Significant management judgement is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and level of future taxable profits together with future tax planning strategies. Further details are contained in note 10 to the Historical Financial Information.

Fair value measurement of share-based payments

The Group has a share-based payment plan and granted equity interests to the Company's directors and the Group's employees. The fair value of the granted equity interests is determined by the back-solve method and equity value allocation based on the option pricing model at the grant date. Significant estimates on assumptions, including expected volatility and risk-free interest rate, are made by the board of directors of the Company. Further details are included in note 27 to the Historical Financial Information.

4. OPERATING SEGMENT INFORMATION

For management purposes, the Group is not organised into business units based on their products and only has one reportable operating segment. Management monitors the operating results of the Group's operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment.

Geographical information

(a) Revenue from external customers

All external revenue of the Group during the Relevant Periods and the six months ended 30 June 2021 was attributable to customers in Mainland China.

(b) Non-current assets

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Mainland China	815,968	1,162,519	1,261,424
Other countries	–	4,235	1,504
	815,968	1,166,754	1,262,928

The non-current asset information above is based on the locations of the assets.

Information about major customers

Revenue from each major customer which accounted for 10% or more of the Group's revenue during the Relevant Periods and the six months ended 30 June 2021 is set out below:

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Customer A	N/A*	48,291	5,289	90,018
Customer B	N/A*	32,852	N/A**	N/A**
Customer C	N/A*	28,223	1,988	37,078
Customer D	N/A*	N/A**	2,218	28,306

* The corresponding revenue is not disclosed as the Group did not generate any revenue for the year ended 31 December 2020.

** The corresponding revenue of the customer is not disclosed as the revenue individually did not account for 10% or more of the Group's revenue during the periods.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Revenue from contracts with customers	–	158,704	12,094	220,690

Revenue from contracts with customers

(a) Disaggregated revenue information

	Year ended 31 December		Six months ended 30 June	
	2020	**2021**	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
			(Unaudited)	
Type of goods				
Sale of products	–	158,704	12,094	220,690
Timing of revenue recognition				
Goods transferred at a point in time	–	158,704	12,094	220,690

Geographical markets

All of the Group's revenue was generated from customers located in Mainland China during the Relevant Periods and the six months ended 30 June 2021.

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sale of products

The performance obligation is satisfied upon acceptance of the goods and payment is generally due within one month to three months.

An analysis of other income and gains is as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	**2021**	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
			(Unaudited)	
Other income and gains				
Government grants*	10,878	4,264	1,327	6,903
Bank interest income	31	9,101	4,418	3,889
Foreign exchange gain, net	–	–	–	2,636
Interest income from a related party	1,164	–	–	–
Others	–	–	–	80
	12,073	13,365	5,745	13,508

* The government grants mainly represent subsidies received from local government authorities to support the Group's research and development activities and operation. During the Relevant Periods and the six months ended 30 June 2021, government grants amounting to RMB200,000, RMB1,000,000, RMB1,800,000 and nil, respectively, were released from deferred government grants (note 23).

6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

		Year ended 31 December		Six months ended 30 June	
		2020	2021	2021	2022
	Notes	*RMB'000*	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Cost of inventories sold		–	48,003	3,311	72,240
Depreciation of property, plant and equipment*		10,480	30,895	11,426	23,260
Depreciation of right-of-use assets*		2,779	8,080	3,290	4,667
Amortisation of intangible assets**		2,623	11,034	3,026	8,181
Research and development costs		236,317	231,567	111,558	169,057
Lease payments not included in the measurement of lease liabilities	*14(c)*	8,295	651	167	1,076
Auditor's remuneration		472	472	239	–
[REDACTED] expenses		**[REDACTED]**	**[REDACTED]**	**[REDACTED]**	**[REDACTED]**
Write-down of inventories to net realisable value***		–	4,187	–	1,181
Impairment of trade receivables****		–	–	–	26
Foreign exchange differences, net		–	5,851	1,163	(2,636)
Loss on disposal of items of property, plant and equipment		11	66	65	3
Government grants	*5*	(10,878)	(4,264)	(1,327)	(6,903)
Bank interest income	*5*	(31)	(9,101)	(4,418)	(3,889)
Interest income from a related party	*5*	(1,164)	–	–	–
Employee benefit expense (excluding directors', chief executive's and supervisors' remuneration *(note 8)*):					
Wages and salaries		22,242	55,599	22,568	37,866
Pension scheme contributions*****		2,610	9,038	2,920	7,884
Staff welfare expenses		1,421	4,997	2,295	2,600
Share-based payment expense		–	9,913	3,291	4,232
		26,273	79,547	31,074	52,582

* The depreciation of property, plant and equipment and right-of-use assets is included in "Cost of sales", "Research and development costs" and "Administrative expenses" in the consolidated statements of profit or loss and other comprehensive income.

** The amortisation of technology know-how and software is included in "Research and development costs" in the consolidated statements of profit or loss and other comprehensive income. The amortisation of deferred development costs is included in "Cost of sales" in the consolidated statements of profit or loss and other comprehensive income.

*** The write-down of inventories to net realisable value is included in "Cost of sales" in the consolidated statements of profit or loss and other comprehensive income.

**** The impairment of trade receivables is included in "Administrative expenses" in the consolidated statements of profit or loss and other comprehensive income.

***** There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Interest on bank loans	11,222	10,895	5,189	5,897
Interest on lease liabilities *(note 14(b))*	597	704	386	264
Others	–	–	–	461
	11,819	11,599	5,575	6,622

8. DIRECTORS', CHIEF EXECUTIVE'S AND SUPERVISORS' REMUNERATION

Directors', chief executive's and supervisors' remuneration for the Relevant Periods and the six months ended 30 June 2021 is as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Fees	–	225	75	150
Other emoluments:				
Salaries, bonuses, allowances and benefits in kind	2,046	7,695	3,741	3,818
Pension scheme contributions	34	246	142	155
Share-based payment expense	–	11,362	3,773	4,849
	2,080	19,303	7,656	8,822
	2,080	19,528	7,731	8,972

During the year ended 31 December 2021, certain directors were granted equity interests, in respect of their services to the Group, further details of which are set out in note 27 to the Historical Financial Information. The fair value of the equity interests granted, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amounts included in the Historical Financial Information for the Relevant Periods and the six months ended 30 June 2021 are included in the above directors', chief executive's and supervisors' remuneration disclosures.

Directors

(a) Independent non-executive directors

Mr. Liu Zhengjun, Mr. Shi Luwen and Mr. Dai Jixiong were appointed as independent non-executive directors in March 2021. The fees paid to independent non-executive directors during the Relevant Periods and the six months ended 30 June 2021 were as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	**2021**	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Mr. Liu Zhengjun	–	75	25	50
Mr. Shi Luwen	–	75	25	50
Mr. Dai Jixiong	–	75	25	50
	–	225	75	150

There were no other emoluments payable to the independent non-executive directors during the Relevant Periods and the six months ended 30 June 2021.

(b) Executive directors, non-executive directors and the chief executive

	Salaries, bonuses, allowances and benefits in kind	**Pension scheme contributions**	**Share-based payment expense**	**Total remuneration**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Year ended 31 December 2020				
Executive directors:				
Ms. Jiang Hua*	938	29	–	967
Dr. Dou Changlin	1,108	5	–	1,113
	2,046	34	–	2,080
Non-executive directors:				
Dr. Li Youxin	–	–	–	–
Ms. Li Li	–	–	–	–
Mr. Liu Yuanchong	–	–	–	–
	–	–	–	–
	2,046	34	–	2,080

	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Share-based payment expense	Total remuneration
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Year ended 31 December 2021				
Executive directors:				
Ms. Jiang Hua*	2,914	149	4,294	7,357
Dr. Dou Changlin	4,615	56	3,042	7,713
	7,529	205	7,336	15,070
Non-executive directors:				
Dr. Li Youxin	–	–	671	671
Ms. Li Li	–	–	1,566	1,566
Mr. Liu Yuanchong	–	–	1,789	1,789
Mr. Chen Jie	–	–	–	–
	–	–	4,026	4,026
	7,529	205	11,362	19,096

	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Share-based payment expense	Total remuneration
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Six months ended 30 June 2022				
Executive directors:				
Ms. Jiang Hua*	1,466	59	1,833	3,358
Dr. Dou Changlin	2,259	74	1,298	3,631
	3,725	133	3,131	6,989
Non-executive directors:				
Dr. Li Youxin	–	–	286	286
Ms. Li Li	–	–	668	668
Mr. Liu Yuanchong	–	–	764	764
Mr. Chen Jie	–	–	–	–
	–	–	1,718	1,718
	3,725	133	4,849	8,707

	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Share-based payment expense	Total remuneration
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Six months ended 30 June 2021 (unaudited)				
Executive directors:				
Ms. Jiang Hua*	1,403	93	1,426	2,922
Dr. Dou Changlin	2,253	28	1,010	3,291
	3,656	121	2,436	6,213
Non-executive directors:				
Dr. Li Youxin	–	–	223	223
Ms. Li Li	–	–	520	520
Mr. Liu Yuanchong	–	–	594	594
Mr. Chen Jie	–	–	–	–
	–	–	1,337	1,337
	3,656	121	3,773	7,550

* Ms. Jiang Hua was appointed as the chief executive of the Company.

Dr. Dou Changlin and Ms. Jiang Hua were appointed as executive directors in November 2019 and June 2020, respectively. Dr. Li Youxin, Ms. Li Li and Mr. Liu Yuanchong were appointed as non-executive directors in June 2020. Mr. Chen Jie was appointed as a non-executive director in January 2021.

Supervisors

	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Share-based payment expense	Total remuneration
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Year ended 31 December 2020				
Ms. Zhang Xiaomei	–	–	–	–
Year ended 31 December 2021				
Ms. Zhang Xiaomei	–	–	–	–
Ms. Ning Xia	166	41	–	207
Ms. Liu Xiangjie	–	–	–	–
	166	41	–	207
Six months ended 30 June 2022				
Ms. Zhang Xiaomei	–	–	–	–
Ms. Ning Xia	93	22	–	115
Ms. Liu Xiangjie	–	–	–	–
	93	22	–	115
Six months ended 30 June 2021 (unaudited)				
Ms. Zhang Xiaomei	–	–	–	–
Ms. Ning Xia	85	21	–	106
Ms. Liu Xiangjie	–	–	–	–
	85	21	–	106

Ms. Zhang Xiaomei, Ms. Ning Xia and Ms. Liu Xiangjie were appointed as supervisors in December 2017, March 2021 and March 2021, respectively.

There was no arrangement under which a director, a supervisor or the chief executive waived or agreed to waive any remuneration during the Relevant Periods and the six months ended 30 June 2021.

9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods and the six months ended 30 June 2021 included one director and the chief executive, details of whose remuneration are set out in note 8 above. Details of the remuneration of the remaining three highest paid employees who are neither a director nor chief executive of the Company during the Relevant Periods and the six months ended 30 June 2021 are as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
			(Unaudited)	
Salaries, bonuses, allowances and benefits in kind	2,481	6,179	2,929	3,173
Pension scheme contributions	46	199	99	105
Share-based payment expense	–	4,223	1,402	1,803
	2,527	10,601	4,430	5,081

The numbers of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands are as follows:

	Number of employees			
	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
			(Unaudited)	
Nil to HK$1,000,000	2	–	–	–
HK$1,000,001 to HK$1,500,000	–	–	1	1
HK$1,500,001 to HK$2,000,000	1	–	1	1
HK$2,000,001 to HK$2,500,000	–	1	–	–
HK$2,500,001 to HK$3,000,000	–	–	1	1
HK$4,000,001 to HK$4,500,000	–	1	–	–
HK$5,500,001 to HK$6,000,000	–	1	–	–
	3	3	3	3

During the year ended 31 December 2021, equity interests were granted to certain non-director and non-chief executive highest paid employees in respect of their services to the Group, further details of which are set out in note 27 to the Historical Financial Information. The fair value of the equity interests granted, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amounts included in the Historical Financial Information for the Relevant Periods and the six months ended 30 June 2021 are included in the above non-director and non-chief executive highest paid employees' remuneration disclosures.

10. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "**CIT Law**"), the Company and the subsidiary which operates in Mainland China are subject to CIT at a rate of 25% on the taxable income.

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of 21% on the taxable income arising in the USA during the Relevant Periods and the six months ended 30 June 2021.

Pursuant to the relevant tax laws of Singapore, the subsidiary which operates in Singapore was subject to corporate income tax at the rate of 17% on the taxable income during the Relevant Periods and the six months ended 30 June 2021.

The Group had no taxable income during the Relevant Periods and the six months ended 30 June 2021.

A reconciliation of the tax expense applicable to loss before tax using the statutory rate of the jurisdictions in which the majority of the Group's subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	Year ended 31 December		Six months ended 30 June	
	2020	**2021**	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
			(Unaudited)	
Loss before tax	(240,538)	(225,417)	(127,927)	(153,295)
Tax charged at the statutory tax rate of 25%	(60,135)	(56,354)	(31,982)	(38,324)
Effect of different tax rates enacted by local authorities	–	1,063	529	62
Additional deductible allowance for research and development costs	(40,593)	(46,793)	(22,869)	(37,800)
Expenses not deductible for tax	278	444	261	73
Exempted debts subject to tax	383	11,039	–	–
Deemed income subject to tax	–	2,330	224	1,028
Deductible temporary difference and tax losses not recognised	100,067	88,271	53,837	74,961
Tax charge at the Group's effective tax rate	–	–	–	–

The Group has accumulated tax losses in Mainland China of RMB1,217,773,000, RMB1,486,030,000 and RMB1,691,246,000 in aggregate as at the end of each of the Relevant Periods, respectively, which can be carried forward for five to ten years to offset against future taxable profits of the entities in which losses were incurred. The Group has deductible temporary differences of RMB2,740,000, RMB66,597,000 and RMB152,451,000 in aggregate as at the end of each of the Relevant Periods, respectively.

The Group has accumulated tax losses in the USA of nil, RMB24,357,000 and RMB32,306,000 in aggregate as at the end of each of the Relevant Periods, respectively, which can be carried forward indefinitely to offset against future taxable profits of the entity in which the losses incurred.

The Group has accumulated tax losses in Singapore of nil, RMB751,000 and RMB1,475,000 in aggregate as at the end of each of the Relevant Periods, respectively, which can be carried forward indefinitely to offset against future taxable profits of the entity in which the losses incurred.

Deferred tax assets have not been recognised in respect of these losses and the temporary differences as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

11. DIVIDENDS

No dividends have been paid or declared by the Company during Relevant Periods.

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

In March 2021, the Company was converted to a joint stock company and a total of 484,000,000 ordinary shares with par value of RMB1.00 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered in the name of the then shareholders. The conversion to ordinary shares with a par value of RMB1.00 each is applied retrospectively for the years ended 31 December 2020 and 2021, and the six months ended 30 June 2022 for the purpose of computation of basic loss per share.

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 39,231,553, 478,577,465, 498,583,294 and 463,432,734 in issue during the Relevant Periods and the six months ended 30 June 2021, respectively.

No adjustment has been made to the basic loss per share amounts presented for the Relevant Periods and the six months ended 30 June 2021 in respect of a dilution as the Group had no potentially dilutive ordinary shares in issue during the Relevant Periods and the six months ended 30 June 2021.

13. PROPERTY, PLANT AND EQUIPMENT

Group

	Buildings	Machinery and equipment	Office equipment	Construction in progress	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
31 December 2020					
At 1 January 2020:					
Cost	–	150,057	900	1,773	152,730
Accumulated depreciation	–	(37,513)	(349)	–	(37,862)
Net carrying amount	–	112,544	551	1,773	114,868
At 1 January 2020, net of accumulated depreciation	–	112,544	551	1,773	114,868
Capital contribution	121,017	223,241	810	1,737	346,805
Additions	–	14,402	357	168	14,927
Disposals	–	(11)	–	–	(11)
Depreciation provided during the year	–	(14,259)	(160)	–	(14,419)
Transfers	–	1,933	8	(1,941)	–
At 31 December 2020, net of accumulated depreciation	121,017	337,850	1,566	1,737	462,170
At 31 December 2020:					
Cost	121,017	389,282	2,075	1,737	514,111
Accumulated depreciation	–	(51,432)	(509)	–	(51,941)
Net carrying amount	121,017	337,850	1,566	1,737	462,170

	Buildings *RMB'000*	Machinery and equipment *RMB'000*	Office equipment *RMB'000*	Construction in progress *RMB'000*	Total *RMB'000*
31 December 2021					
At 1 January 2021:					
Cost	121,017	389,282	2,075	1,737	514,111
Accumulated depreciation	–	(51,432)	(509)	–	(51,941)
Net carrying amount	121,017	337,850	1,566	1,737	462,170
At 1 January 2021, net of accumulated depreciation	121,017	337,850	1,566	1,737	462,170
Additions	194	71,716	5,940	12,468	90,318
Disposals	–	(66)	–	–	(66)
Depreciation provided during the year	(4,047)	(42,862)	(671)	–	(47,580)
Transfers	–	1,763	–	(1,763)	–
At 31 December 2021, net of accumulated depreciation	117,164	368,401	6,835	12,442	504,842
At 31 December 2021:					
Cost	121,211	461,986	8,011	12,442	603,650
Accumulated depreciation	(4,047)	(93,585)	(1,176)	–	(98,808)
Net carrying amount	117,164	368,401	6,835	12,442	504,842

	Buildings *RMB'000*	Machinery and equipment *RMB'000*	Office equipment *RMB'000*	Construction in progress *RMB'000*	Total *RMB'000*
30 June 2022					
At 1 January 2022:					
Cost	121,211	461,986	8,011	12,442	603,650
Accumulated depreciation	(4,047)	(93,585)	(1,176)	–	(98,808)
Net carrying amount	117,164	368,401	6,835	12,442	504,842
At 1 January 2022, net of accumulated depreciation	117,164	368,401	6,835	12,442	504,842
Additions	168	27,734	399	55,917	84,218
Disposals	–	(1)	(2)	–	(3)
Depreciation provided during the period	(2,029)	(23,764)	(614)	-	(26,407)
Transfers	–	20,556	–	(20,556)	–
At 30 June 2022, net of accumulated depreciation	115,303	392,926	6,618	47,803	562,650
At 30 June 2022:					
Cost	121,379	510,268	8,407	47,803	687,857
Accumulated depreciation	(6,076)	(117,342)	(1,789)	–	(125,207)
Net carrying amount	115,303	392,926	6,618	47,803	562,650

Company

	Buildings *RMB'000*	Machinery and equipment *RMB'000*	Office equipment *RMB'000*	Construction in progress *RMB'000*	Total *RMB'000*
31 December 2020					
At 1 January 2020:					
Cost	–	150,057	900	1,773	152,730
Accumulated depreciation	–	(37,513)	(349)	–	(37,862)
Net carrying amount	–	112,544	551	1,773	114,868
At 1 January 2020, net of accumulated depreciation	–	112,544	551	1,773	114,868
Capital contribution	121,017	223,241	810	1,737	346,805
Additions	–	14,402	357	168	14,927
Disposals	–	(11)	–	–	(11)
Depreciation provided during the year	–	(14,259)	(160)	–	(14,419)
Transfers	–	1,933	8	(1,941)	–
At 31 December 2020, net of accumulated depreciation	121,017	337,850	1,566	1,737	462,170
At 31 December 2020:					
Cost	121,017	389,282	2,075	1,737	514,111
Accumulated depreciation	–	(51,432)	(509)	–	(51,941)
Net carrying amount	121,017	337,850	1,566	1,737	462,170

	Buildings *RMB'000*	Machinery and equipment *RMB'000*	Office equipment *RMB'000*	Construction in progress *RMB'000*	Total *RMB'000*
31 December 2021					
At 1 January 2021:					
Cost	121,017	389,282	2,075	1,737	514,111
Accumulated depreciation	–	(51,432)	(509)	–	(51,941)
Net carrying amount	121,017	337,850	1,566	1,737	462,170
At 1 January 2021, net of accumulated depreciation	121,017	337,850	1,566	1,737	462,170
Additions	194	53,704	5,322	12,468	71,688
Disposals	–	(66)	–	–	(66)
Depreciation provided during the year	(4,047)	(41,583)	(558)	–	(46,188)
Transfers	–	1,763	–	(1,763)	–
At 31 December 2021, net of accumulated depreciation	117,164	351,668	6,330	12,442	487,604
At 31 December 2021:					
Cost	121,211	443,973	7,393	12,442	585,019
Accumulated depreciation	(4,047)	(92,305)	(1,063)	–	(97,415)
Net carrying amount	117,164	351,668	6,330	12,442	487,604

	Buildings *RMB'000*	Machinery and equipment *RMB'000*	Office equipment *RMB'000*	Construction in progress *RMB'000*	Total *RMB'000*
30 June 2022					
At 1 January 2022:					
Cost	121,211	443,973	7,393	12,442	585,019
Accumulated depreciation	(4,047)	(92,305)	(1,063)	–	(97,415)
Net carrying amount	117,164	351,668	6,330	12,442	487,604
At 1 January 2022, net of accumulated depreciation	117,164	351,668	6,330	12,442	487,604
Additions	168	27,654	399	55,858	84,079
Disposals	–	(1)	(2)	–	(3)
Depreciation provided during the period	(2,029)	(22,705)	(536)	-	(25,270)
Transfers	–	20,556	–	(20,556)	–
At 30 June 2022, net of accumulated depreciation	115,303	377,172	6,191	47,744	546,410
At 30 June 2022:					
Cost	121,379	492,174	7,791	47,744	669,088
Accumulated depreciation	(6,076)	(115,002)	(1,600)	–	(122,678)
Net carrying amount	115,303	377,172	6,191	47,744	546,410

As at 31 December 2021 and 30 June 2022, the Group's and the Company's property, plant and equipment with carrying values of RMB200,011,000 and RMB191,829,000 were pledged to secure the bank loans (note 22).

14. LEASES

The Group and the Company as a lessee

The Group has lease contracts for various items of laboratory and office premises, and machinery and equipment used in its operations. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 38 years, and no ongoing payments will be made under the terms of these land leases. Leases of laboratory and office premises have lease terms between 1.5 and 5 years, while machinery and equipment generally have lease terms between 1.5 and 5 years. Other equipment generally has lease terms of 12 months or less. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amounts of right-of-use assets and the movements during the Relevant Periods are as follows:

Group

	Leasehold land *RMB'000*	**Laboratory and office premises** *RMB'000*	**Machinery and equipment** *RMB'000*	**Total** *RMB'000*
At 1 January 2020	–	895	7,041	7,936
Capital contribution	4,544	–	–	4,544
Additions	–	8,171	–	8,171
Depreciation charge	(9)	(1,976)	(1,760)	(3,745)
At 31 December 2020 and 1 January 2021	4,535	7,090	5,281	16,906
Additions	–	6,314	3,185	9,499
Depreciation charge	(111)	(5,134)	(4,404)	(9,649)
Exchange realignment	–	(23)	(15)	(38)
At 31 December 2021 and 1 January 2022	4,424	8,247	4,047	16,718
Additions	-	-	2,272	2,272
Depreciation charge	(56)	(3,124)	(2,174)	(5,354)
Exchange realignment	–	42	27	69
At 30 June 2022	4,368	5,165	4,172	13,705

Company

	Leasehold land *RMB'000*	**Laboratory and office premises** *RMB'000*	**Machinery and equipment** *RMB'000*	**Total** *RMB'000*
At 1 January 2020	–	895	7,041	7,936
Capital contribution	4,544	–	–	4,544
Additions	–	6,078	–	6,078
Depreciation charge	(9)	(1,743)	(1,760)	(3,512)
At 31 December 2020 and 1 January 2021	4,535	5,230	5,281	15,046
Additions	–	1,383	–	1,383
Depreciation charge	(111)	(2,121)	(1,760)	(3,992)
At 31 December 2021 and 1 January 2022	4,424	4,492	3,521	12,437
Additions	-	-	2,272	2,272
Depreciation charge	(56)	(1,123)	(1,107)	(2,286)
At 30 June 2022	4,368	3,369	4,686	12,423

As at 31 December 2021 and 30 June 2022, the Group's and the Company's right-of-use assets with carrying values of RMB4,424,000 and RMB4,368,000 were pledged to secure the bank loans (note 22).

(b) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

Group

	As at 31 December		As at 30 June
	2020	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000*
Carrying amount at 1 January	8,251	16,133	14,523
New leases	8,171	9,499	2,272
Accretion of interest recognised during the year/period	597	704	264
Payments	(886)	(10,130)	(5,847)
Exemption of payments	–	(1,641)	–
Exchange realignment	–	(42)	91
Carrying amount at the end of year/period	16,133	14,523	11,303
Analysed into:			
Current portion	7,647	10,019	9,980
Non-current portion	8,486	4,504	1,323

Company

	As at 31 December		As at 30 June
	2020	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000*
Carrying amount at 1 January	8,251	14,011	8,801
New leases	6,078	1,383	2,272
Accretion of interest recognised during the year/period	568	452	219
Payments	(886)	(5,404)	(1,635)
Exemption of payments	–	(1,641)	–
Carrying amount at the end of year/period	14,011	8,801	9,657
Analysed into:			
Current portion	6,233	4,297	8,467
Non-current portion	7,778	4,504	1,190

The maturity analysis of lease liabilities is disclosed in note 33 to the Historical Financial Information.

(c) The amounts recognised in profit or loss in relation to leases are as follows:

Group

	Year ended 31 December		Six months ended 30 June	
	2020	**2021**	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Interest on lease liabilities	597	704	386	264
Depreciation charge of right-of-use assets	2,779	8,080	3,290	4,667
Expense relating to short-term leases (included in cost of sales, research and development costs and administrative expenses)	8,295	651	167	1,076
Total amount recognised in profit or loss	11,671	9,435	3,843	6,007

Company

	Year ended 31 December		Six months ended 30 June	
	2020	**2021**	**2021**	**2022**
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Interest on lease liabilities	568	452	244	219
Depreciation charge of right-of-use assets	2,546	2,423	679	1,600
Expense relating to short-term leases (included in cost of sales, research and development costs and administrative expenses)	8,295	619	155	1,076
Total amount recognised in profit or loss	11,409	3,494	1,078	2,895

(d) The total cash outflow for leases is disclosed in note 28(c) to the Historical Financial Information.

15. INTANGIBLE ASSETS

Group and Company

	Technology know-how *RMB'000*	Deferred development costs *RMB'000*	Software *RMB'000*	Total *RMB'000*
31 December 2020				
Cost at 1 January 2020, net of accumulated amortisation	15,300	201,426	–	216,726
Capital contribution	–	–	35	35
Addition	–	112,105	–	112,105
Amortisation provided during the year	(3,600)	–	–	(3,600)
At 31 December 2020	11,700	313,531	35	325,266
At 31 December 2020:				
Cost	36,000	313,531	35	349,566
Accumulated amortisation	(24,300)	–	–	(24,300)
Net carrying amount	11,700	313,531	35	325,266
31 December 2021				
Cost at 1 January 2021, net of accumulated amortisation	11,700	313,531	35	325,266
Addition	–	253,715	–	253,715
Amortisation provided during the year	(3,600)	(9,375)	(4)	(12,979)
At 31 December 2021	8,100	557,871	31	566,002
At 31 December 2021:				
Cost	36,000	567,246	35	603,281
Accumulated amortisation	(27,900)	(9,375)	(4)	(37,279)
Net carrying amount	8,100	557,871	31	566,002
30 June 2022				
Cost at 1 January 2022, net of accumulated amortisation	8,100	557,871	31	566,002
Addition	–	95,930	–	95,930
Amortisation provided during the period	(1,800)	(6,920)	(2)	(8,722)
At 30 June 2022	6,300	646,881	29	653,210
At 30 June 2022:				
Cost	36,000	663,176	35	699,211
Accumulated amortisation	(29,700)	(16,295)	(6)	(46,001)
Net carrying amount	6,300	646,881	29	653,210

(a) Impairment testing of deferred development costs

The intangible assets of the Group include the deferred development costs which are the expenditure incurred in the development phase of each project. The management of the Company tests the deferred development costs which are not yet available for use for impairment at least annually, and whenever there is an indication that the unit may be impaired, by comparing their carrying amount with their recoverable amounts.

The recoverable amounts of the deferred development costs were determined based on the value in use. The value in use of the deferred development costs was determined by using the risk-adjusted net present value method through taking into account the possibility of success, using cash flow projections based on financial budgets approved by the management of the Company covering fourteen to fifteen years which consist of development periods up to three years, growth and mature periods of seven to ten years and fast-declining periods of five years, reflecting the periods before reaching a perpetual growth mode. Considering it generally takes longer for a biotechnology company to reach a perpetual growth mode compared to companies in other industries and taking into account of the expected timing of commercialisation, market size and penetration of related products, the management of the Company prepared the financial forecasts up to the year of 2035 in the impairment tests. Other key assumptions used in the value-in-use calculations are listed as follows:

	31 December 2020	**31 December 2021**
Discount rates	15%	15%
Budgeted gross margins	86%	86%
Terminal growth rates	-3%	-3%

Discount rates – The discount rates used are before tax and reflect specific risks relating to deferred development costs.

Budgeted gross margins – The basis used to determine the value assigned to budgeted gross margins is the market gross margins where the biopharmaceuticals are located, taking into account the expected efficiency improvements and expected market development.

Terminal growth rates – The terminal growth rates used to extrapolate the cash flows beyond the forecast period are based on the estimate to the life cycle of biosimilars and the characteristics of biopharmaceuticals.

The above parameters keep stable for the years ended 31 December 2020 and 2021 because the Group's products are all biological products and apply similar operation model and production flow and are on the basis of insignificant fluctuations about economical factors.

As at 31 December 2020 and 2021, the recoverable amount of deferred development costs and the carrying amount of each project are listed as follows:

	Recoverable amounts	Carrying amounts	Headroom
	RMB'000	*RMB'000*	*RMB'000*
31 December 2020			
BA1101	1,399,830	234,341	1,165,489
BA6101	182,680	73,564	109,116
BA9101	80,945	5,626	75,319
	1,663,455	313,531	1,349,924
31 December 2021			
BA6101	294,610	171,085	123,525
BA9101	96,626	40,307	56,319
BA1102	104,565	74,601	29,964
	495,801	285,993	209,808

The Group did not perform impairment test for deferred development costs as at 30 June 2022, because there was no indication that any project might be impaired as at 30 June 2022, and the Group performs impairment test annually at December year-end in accordance with IAS 36 *Impairment of assets*.

(b) Sensitivity to changes in key assumptions

The following table sets forth the impact of reasonably possible changes in each of the key assumptions on, with all other variables held constant, impairment testing of deferred development costs of the Group as at the dates indicated.

	Recoverable amount of the deferred development costs exceeding their carrying amount decrease by	
	31 December 2020	31 December 2021
	RMB'000	*RMB'000*
Possible changes of key assumptions		
Discount rates increased by 1%	99,439	33,653
Budgeted gross margins decreased by 1%	37,525	17,939
Terminal growth rate decreased by 1%	3,851	1,585
Expected market shares decreased by 1%	102,273	10,489

With regard to the assessment of value in use, the management of the Company believes that no reasonably possible changes in any of the key assumptions would cause the recoverable amounts of deferred development costs to be materially lower than their carrying amounts.

16. INVENTORIES

Group and Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Raw materials	19,672	53,926	98,068
Work in progress	–	12,525	28,602
Finished goods	–	32,389	14,207
	19,672	98,840	140,877

17. TRADE AND NOTES RECEIVABLES

Group and Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Trade receivables	–	78,057	109,848
Notes receivable	700	29,210	29,208
	700	107,267	139,056
Impairment	–	–	(26)
	700	107,267	139,030

The Group's trading terms with its customers are mainly on credit. The credit period is generally one to three months, depending on the specific payment terms in each contract. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. In view of the aforementioned and the fact that the Group's trade receivables relate to a large number of diversified customers, there is no significant concentration of credit risk. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

As at the end of each of the Relevant Periods, notes receivable of RMB700,000, RMB29,210,000 and RMB29,208,000, whose fair values approximated to their carrying values, were classified as financial assets at fair value through other comprehensive income under IFRS 9. The fair value changes of these notes receivable at fair value through other comprehensive income were insignificant.

An ageing analysis of the trade receivables as at 31 December 2021 and 30 June 2022, based on the invoice date and net of loss allowance, is as follows:

	As at 31 December 2021	As at 30 June 2022
	RMB'000	*RMB'000*
Within 3 months	77,858	79,933
3 to 6 months	113	1,061
6 to 12 months	86	28,803
1 to 2 years	–	25
	78,057	109,822

The movements in the loss allowance for impairment of trade receivables are as follows:

	As at 31 December 2021	As at 30 June 2022
	RMB'000	*RMB'000*
At beginning of year/period	–	–
Impairment losses	–	26
At end of year/period	–	26

An impairment analysis is performed at the end of the reporting period using a provision matrix to measure expected credit losses. The provision rates are based on ageing for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome and reasonable and supportable information that is available at the end of the reporting period about past events, current conditions and forecasts of future economic conditions. As at 31 December 2021, the loss allowance of the Group and the Company was assessed to be minimal and the expected credit loss rate for trade receivables was close to zero.

Set out below is the information about the credit risk exposure on the Group's and the Company's trade receivables using a provision matrix:

As at 30 June 2022

	Within 1 year	1 year to 2 years	Total
Expected credit loss rate	0.00%	50.00%	0.02%
Gross carrying amount (RMB'000)	109,797	51	109,848
Expected credit losses (RMB'000)	–	26	26

As at the end of each of the Relevant Periods, the Group and the Company endorsed certain notes receivable accepted by certain banks in the PRC (the "**Endorsed Notes**") to certain of its suppliers in order to settle the trade and other payables due to such suppliers with carrying amounts in aggregate of RMB12,482,000, RMB2,487,000 and RMB12,672,000, respectively (the "**Endorsement**"). In addition, the Group and the Company discounted certain notes receivable accepted by certain banks in the PRC (the "**Discounted Notes**") to certain banks to finance its operating cash flows with carrying amounts in aggregate of nil, nil and RMB32,602,000, respectively (the "**Discount**"). The Endorsed Notes and the Discounted Notes had a maturity from one to six months as at the end of each of the Relevant Periods. In accordance with the Law of Negotiable Instruments and relevant discounting arrangements with certain banks in the PRC, the holders of the Endorsed Notes and the Discounted Notes have a right of recourse against the Group and the Company if the PRC banks default (the "**Continuing Involvement**").

In the opinion of the directors, the Group and the Company has transferred substantially all risks and rewards relating to certain Endorsed Notes with amounts of RMB11,782,000, RMB2,477,000 and RMB7,930,000 and certain Discounted Notes with amounts of nil, nil and RMB25,922,000 accepted by large and reputable banks as at the end of each of the Relevant Periods, respectively (the "**Derecognised Notes**"). Accordingly, it has derecognised the full carrying amounts of the Derecognised Notes. The maximum exposure to loss from the Group's and the Company's Continuing Involvement in the Derecognised Notes and the undiscounted cash flows to repurchase these Derecognised Notes is equal to their carrying amounts. In the opinion of the directors, the fair values of the Group's and the Company's Continuing Involvement in the Derecognised Notes are not significant.

For the rest of the Endorsed Notes and the Discounted Notes, the directors believe that the Group has retained the substantial risks and rewards, which include default risks relating to such Endorsed Notes and Discounted Notes, and accordingly, it continued to recognise the full carrying amounts of the Endorsed Notes and the Discounted Notes. Subsequent to the Endorsement or the Discount, the Group and the Company did not retain any rights on the use of the Endorsed Notes or the Discounted Notes, including the sale, transfer or pledge of the Endorsed Notes or the Discounted Notes to any other third parties. As at the end of each of the Relevant Periods, the aggregate carrying amounts of the trade and other payables settled by such Endorsed Notes to which the suppliers have recourse were RMB700,000, RMB10,000 and RMB4,742,000, and the aggregate carrying amounts financed by such Discounted Notes to which the banks have recourse were nil, nil and RMB6,680,000, respectively.

18. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

Group

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Prepayments	33,738	51,592	54,624
Value-added tax recoverable	29,840	15,472	4,642
Other receivables	400	2,813	660
Deferred [**REDACTED**] expenses	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Other current assets	4,083	5,033	4,559
	68,061	75,328	68,112

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As at the end of each of the Relevant Periods, the loss allowance of the Group was assessed to be minimal and the expected credit loss rate for other receivables was close to zero.

Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Prepayments	33,112	51,588	53,858
Value-added tax recoverable	29,687	12,341	1,269
Other receivables	377	2,802	609
Deferred [**REDACTED**] expenses	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Other current assets	3,413	3,865	3,450
	66,589	71,014	62,813

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As at the end of each of the Relevant Periods, the loss allowance of the Company was assessed to be minimal and the expected credit loss rate for other receivables was close to zero.

19. CASH AND CASH EQUIVALENTS, TIME DEPOSITS OVER THREE MONTHS AND PLEDGED DEPOSITS

Group

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Cash and bank balances	3,629	558,415	314,429
Time deposits	–	100,000	100,000
	3,629	658,415	414,429
Less:			
Pledged deposits for notes payable *(note 20)*	–	(44,853)	(2,188)
Non-pledged time deposits over three months	–	(81,859)	(100,000)
Cash and cash equivalents	3,629	531,703	312,241
Denominated in:			
RMB	3,629	281,308	297,805
United States dollar ("**US$**")	–	250,094	14,034
Singapore dollar ("**SG$**")	–	301	402
Cash and cash equivalents	3,629	531,703	312,241

Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Cash and bank balances	1,915	529,728	301,101
Time deposits	–	100,000	100,000
	1,915	629,728	401,101
Less:			
Pledged deposits for notes payable *(note 20)*	–	(44,853)	(2,188)
Non-pledged time deposits over three months	–	(81,859)	(100,000)
Cash and cash equivalents	1,915	503,016	298,913
Denominated in:			
RMB	1,915	261,102	297,780
US$	–	241,914	1,133
Cash and cash equivalents	1,915	503,016	298,913

Time deposits over three months were denominated in RMB as at the end of each of the Relevant Periods. The RMB is not freely convertible into other currencies, however, under Mainland China's Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group and the Company are permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short term time deposits are made for varying periods of between one day and twelve months depending on the immediate cash requirements of the Group, and earn interest at the respective short term time deposit rates. The bank balances and pledged deposits are deposited with creditworthy banks with no recent history of default.

20. TRADE AND NOTES PAYABLES

Group

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Trade payables	91,585	93,861	118,351
Notes payable	–	44,853	2,188
	91,585	138,714	120,539

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Within 3 months	83,102	75,185	97,889
3 to 6 months	5,084	8,453	13,134
6 to 12 months	3,184	5,593	5,589
1 to 2 years	198	4,548	941
Over 2 years	17	82	798
	91,585	93,861	118,351

Trade payables are non-interest-bearing and are normally settled on 90-day terms.

The maturity of the Group's notes payable is within six months.

As at 31 December 2021 and 30 June 2022, the Group's notes payable were secured by certain of the Group's deposits amounting to approximately RMB44,853,000 and RMB2,188,000 (note 19).

Included in the Group's notes payable were amounts due to a related party of RMB15,740,000 as at 31 December 2021.

Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Trade payables	90,368	92,824	117,896
Notes payable	–	44,853	2,188
	90,368	137,677	120,084

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Within 3 months	81,885	74,193	97,450
3 to 6 months	5,084	8,414	13,126
6 to 12 months	3,184	5,587	5,581
1 to 2 years	198	4,548	941
Over 2 years	17	82	798
	90,368	92,824	117,896

Trade payables are non-interest-bearing and are normally settled on 90-day terms.

The maturity of the Company's notes payable is within six months.

As at 31 December 2021 and 30 June 2022, the Company's notes payable were secured by certain of the Company's deposits amounting to approximately RMB44,853,000 and RMB2,188,000 (note 19).

Included in the Company's notes payable were amounts due to a related party of RMB15,740,000 as at 31 December 2021.

21. OTHER PAYABLES AND ACCRUALS

Group

		As at 31 December		As at 30 June
		2020	2021	2022
	Notes	*RMB'000*	*RMB'000*	*RMB'000*
Payroll payables		6,355	21,408	21,785
Other payables	*(a)*	5,538	7,509	9,621
Taxes payable other than income tax		294	5,870	10,169
Accrued promotion expenses		–	42,305	90,562
Accrued **[REDACTED]** expenses		**[REDACTED]**	**[REDACTED]**	**[REDACTED]**
Contract liabilities	*(b)*	–	1,290	3,393
		12,187	79,024	151,318

Notes:

(a) Other payables are non-interest-bearing and repayable on demand.

(b) Contract liabilities include short-term advances received to deliver products. The increase in contract liabilities during the Relevant Periods was mainly due to the increase in short-term advances received from customers in relation to the sale of products.

Company

		As at 31 December		As at 30 June
		2020	2021	2022
	Notes	*RMB'000*	*RMB'000*	*RMB'000*
Payroll payables		5,623	18,851	19,884
Other payables	*(a)*	5,522	6,442	9,513
Taxes payable other than income tax		286	5,854	10,131
Accrued promotion expenses		–	42,305	90,562
Accrued **[REDACTED]** expenses		**[REDACTED]**	**[REDACTED]**	**[REDACTED]**
Contract liabilities	*(b)*	–	1,290	3,393
		11,431	75,384	149,271

Notes:

(a) Other payables are non-interest-bearing and repayable on demand.

(b) Contract liabilities include short-term advances received to deliver products. The increase in contract liabilities during the Relevant Periods was mainly due to the increase in short-term advances received from customers in relation to the sale of products.

22. INTEREST-BEARING BANK LOANS

Group and Company

	Effective interest rate	Maturity	As at 31 December 2020	2021	As at 30 June 2022
	(%)		*RMB'000*	*RMB'000*	*RMB'000*
Current					
Current portion of long-term bank loans — secured	5-year LPR+0.05	2022	–	10,000	20,000
Discounted notes receivable	1.75	2022	–	–	2,375
	2.11	2022	–	–	1,305
	1.96	2022	–	–	3,000
			–	10,000	26,680
Non-current					
Bank loans — secured	5-year LPR+0.05	2023-2026	–	240,000	225,000
Analysed into:					
Bank loans repayable:					
Within one year			–	10,000	26,680
In the second year			–	30,000	40,000
In the third to fifth years, inclusive			–	210,000	185,000
			–	250,000	251,680

The Group's and the Company's bank loans are trade in nature and are secured by:

(i) mortgages over the Group's and the Company's property, plant and equipment, which had net carrying values of approximately RMB200,011,000 and RMB191,829,000 as at 31 December 2021 and 30 June 2022 (note 13); and

(ii) mortgages over the Group's and the Company's right-of-use assets, which had net carrying values of approximately RMB4,424,000 and RMB4,368,000 as at 31 December 2021 and 30 June 2022 (note 14).

In addition, the Group's related parties have guaranteed the bank loans as at 31 December 2021 and 30 June 2022 (note 30(b)) and such guarantee will be released upon the [**REDACTED**] of the Company.

23. GOVERNMENT GRANTS

Group and Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
At beginning of the year/period	1,200	2,800	1,800
Grants received during the year/period	1,800	–	–
Amounts released to profit or loss	(200)	(1,000)	(1,800)
At end of the year/period	2,800	1,800	–

The grants were related to the subsidies received from local government authorities to support the Group's research and development activities with conditions to fulfil. The grants were recognised in profit or loss when the conditions are met.

24. OTHER NON-CURRENT LIABILITIES

The Company entered into an agreement with OcuMension Therapeutics (Zhejiang) Co., Ltd. ("**OcuMension**") on 28 October 2020. The amendment was amended by a supplemental agreement dated 31 May 2021, pursuant to which the Company agreed to conduct certain initial stages of the Phase 3 clinical trial and commercial production and obtain the biologic licence application of BA9101 and OcuMension agreed to complete the rest of Phase 3 clinical trial and to promote and commercialise BA9101 in China. Other non-current liabilities represent the considerations received for the collaboration arrangement.

25. SHARE CAPITAL/PAID-IN CAPITAL

Group and Company

Share capital

	Number of ordinary shares	Share capital
		RMB'000
At 1 January 2020, 31 December 2020 and 1 January 2021	–	–
Issue of ordinary shares upon conversion into a joint stock company *(note (c))*	484,000,000	484,000
Issue of ordinary shares *(note (d))*	14,583,294	14,583
At 31 December 2021, 1 January 2022 and 30 June 2022	498,583,294	498,583

Paid-in capital

	Paid-in capital *RMB'000*
At 1 January 2020	10,000
Capital contribution from a shareholder *(note (a))*	350,000
At 31 December 2020 and 1 January 2021	360,000
Capital contribution from shareholders *(note (b))*	123,199
Conversion into a joint stock company *(note (c))*	(483,199)
At 31 December 2021, 1 January 2022 and 30 June 2022	–

Notes:

(a) On 8 December 2020, the Company entered into a capital injection agreement with Shandong Luye Pharmaceutical Co., Ltd. ("**Shandong Luye**"), pursuant to which total capital of approximately RMB1,149,654,000 was injected into the Company, with RMB350,000,000 and RMB799,654,000 credited to the Company's paid-in capital and other reserves, respectively. The total capital consists of cash amounting to RMB798,270,000 to subscribe paid-in capital of approximately RMB243,029,000, and property, plant and equipment, leasehold land and intangible assets amounting to approximately RMB346,805,000, RMB4,544,000 and RMB35,000, respectively, to subscribe paid-in capital of approximately RMB106,971,000.

(b) In December 2020 and January 2021, the Company entered into capital injection agreements with 18 shareholders, pursuant to which a total capital of approximately RMB876,618,000 was injected into the Company, with approximately RMB75,639,000 and RMB800,979,000 credited to the Company's paid-in capital and other reserves, respectively. The consideration was fully paid in cash by January 2021.

Pursuant to the share-based payment arrangement, which is set out in note 27, total capital of RMB142,680,000 was injected into the Company by Yantai Bolian Investment Center Limited Partnership, Yantai Bosheng Investment Center Limited Partnership and Yantai Bofa Investment Center Limited Partnership, with RMB47,560,000 and RMB95,120,000 credited to the Company's paid-in capital and other reserves, respectively. The consideration was fully paid in cash by January 2021.

(c) In March 2021, the Company converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company as of the conversion base date, including paid-in capital, other reserves and accumulated losses, amounting to approximately RMB1,449,556,000 were converted into 484,000,000 ordinary shares of RMB1.00 each. The excess of the net assets converted over the nominal value of the ordinary shares was credited to the Company's share premium.

(d) In August and September 2021, the Company entered into capital injection agreements with 5 shareholders, pursuant to which total capital of approximately RMB210,915,000 was injected into the Company with approximately RMB14,583,000 and RMB196,332,000 credited to the Company's share capital and share premium, respectively. The consideration was fully paid in cash by September 2021.

26. RESERVES

Group

The amounts of the Group's reserves and the movements therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

Share premium

The share premium of the Group represents the share premium contributed by the shareholders of the Company after its conversion into a joint stock company.

Other reserves

Other reserves of the Group represent the share premium contributed by the shareholders of the Company before its conversion into a joint stock company, exempted payables to shareholders and share-based payment reserve.

Safety production reserve

The Group has appropriated a certain amount of accumulated losses to the safety production reserve fund for safety production expense purposes as required by directives issued by the relevant PRC government authorities. The Group charged the safety production expense to profit or loss when such expense was incurred, and at the same time an equal amount of special reserve fund was utilised and transferred back to accumulated losses.

Exchange fluctuation reserve

The exchange fluctuation reserve represents exchange differences arising from the translation of the financial statements of foreign operations whose functional currencies are different from the Group's presentation currency.

Company

	Share premium *RMB'000*	Other reserves *RMB'000*	Safety production reserve *RMB'000*	Accumulated losses *RMB'000*	Total *RMB'000*
At 1 January 2020	–	–	–	(439,057)	(439,057)
Loss and total comprehensive loss for the year	–	–	–	(235,986)	(235,986)
Capital contribution from a shareholder	–	799,654	–	–	799,654
Exemption of payables to a former shareholder	–	1,530	–	–	1,530
At 31 December 2020 and 1 January 2021	–	801,184	–	(675,043)	126,141
Loss and total comprehensive loss for the year	–	–	–	(184,709)	(184,709)
Capital contribution from shareholders before conversion into a joint stock company	–	896,099	–	–	896,099
Conversion into a joint stock company	965,556	(1,697,283)	–	730,926	(801)
Capital contribution from shareholders after conversion into a joint stock company	196,332	–	–	–	196,332
Exemption of payables to a shareholder	–	44,155	–	–	44,155
Appropriation to safety production reserve	–	–	2,507	(2,507)	–
Safety production reserve used	–	–	(491)	491	–
Share-based payment arrangements	–	21,275	–	–	21,275
At 31 December 2021 and 1 January 2022	1,161,888	65,430	2,016	(130,842)	1,098,492
Loss and total comprehensive loss for the period	–	–	–	(137,263)	(137,263)
Appropriation to safety production reserve	–	–	3,003	(3,003)	–
Safety production reserve used	–	–	(863)	863	–
Share-based payment arrangements	–	9,081	–	–	9,081
At 30 June 2022	1,161,888	74,511	4,156	(270,245)	970,310

27. SHARE-BASED PAYMENT

In December 2020, the board of directors of the Company passed a resolution to grant equity interests of the Company to the eligible employees (including directors) in order to provide incentives and rewards to participants for the business development of the Group. Subsequently, Yantai Bolian Investment Center Limited Partnership ("**Yantai Bolian**"), Yantai Bosheng Investment Center Limited Partnership ("**Yantai Bosheng**") and Yantai Bofa Investment Center Limited Partnership ("**Yantai Bofa**"), three employee incentive platforms established in the PRC, subscribed paid-in capital of RMB21,380,000, RMB14,930,000 and RMB11,250,000 of the Company for total considerations of RMB64,140,000, RMB44,790,000 and RMB33,750,000, respectively.

On 27 January 2021, 4.4247% of the then equity interest in the Company was granted to 36 selected directors and employees of the Company for a consideration of RMB64,140,000 through Yantai Bolian. 3.0898% of the then equity interest in the Company was granted to 45 selected directors and employees of the Company for a consideration of RMB44,790,000 through Yantai Bosheng. 2.3282% of the then equity interest in the Company was granted to 47 selected directors and employees of the Company for a consideration of RMB33,750,000 through Yantai Bofa. The management has the power to select the eligible employees and the Group derive benefits from the services of the employees who have been granted the then equity interest through their continued employment with the Group.

Pursuant to the partnership agreements of Yantai Bolian, Yantai Bosheng and Yantai Bofa (collectively referred to as the "**ESOP Entities**"), (i) the ESOP Entities shall not dispose of any of the shares they held within 36 months immediately following the date of the Company's **[REDACTED]** (the "**ESOP Lock-up Period**"); and (ii) a partner is entitled to direct the ESOP Entities to dispose of his/her share of the shares held by the ESOP Entities (based on his/her shareholding percentage in the ESOP Entities) (the "**ESOP Shares**") in the following manner: (a) 25% of his/her ESOP Shares upon the expiry of 12 months following the day after the ESOP Lock-up Period; (b) 50% of his/her ESOP Shares upon the expiry of 24 months following the day after the ESOP Lock-up Period; (c) 75% of his/her ESOP Shares upon the expiry of 36 months following the day after the ESOP Lock-up Period; and (d) 100% of his/her ESOP Shares upon the expiry of 48 months following the day after the ESOP Lock-up Period. If a person cease to be qualified as a partner during the vesting period, the general partner shall have the right to purchase or appoint other eligible employees to purchase the share of that person at cost or cost plus market interest. In August 2021, the ESOP Lock-up Period was revised as 12 months immediately following the date of the Company's **[REDACTED]** pursuant to the updated partnership agreements.

The fair value of services received in return for equity interests granted is measured by reference to the fair value of the equity interests granted less the consideration received by the Group.

The fair value of the equity interests granted is determined by the back-solve method and equity value allocation based on the option pricing model at the grant date. The following table lists the inputs to the model used:

	Year ended 31 December 2021
Risk-free interest rate (%)	2.9%
Volatility (%)	42.0%

During the year ended 31 December 2021 and the six months ended 30 June 2021 and 2022, a share-based payment expense of RMB21,275,000, RMB7,064,000 and RMB9,081,000 was charged to profit or loss.

28. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

The Group had non-cash additions to right-of-use assets of RMB8,171,000, RMB9,499,000 RMB2,272,000 and non-cash additions to lease liabilities of RMB8,171,000, RMB9,499,000 and RMB2,272,000 during the Relevant Periods, in respect of lease arrangements for laboratory and office premises, and machinery and equipment.

The Group had non-cash debt exemption from shareholders of RMB1,530,000 and RMB44,155,000 during the years ended 31 December 2020 and 2021, respectively.

The Group had non-cash additions to property, plant and equipment of RMB346,805,000, right-of-use assets of RMB4,544,000 and intangible assets of RMB35,000 during the year ended 31 December 2020 due to capital contribution.

The Group had non-cash additions to interest-bearing bank loans of RMB250,000,000 and non-cash decreases of amounts due to related parties of RMB250,000,000 during the year ended 31 December 2021 due to debt transfer.

The Group had non-cash additions to other non-current liabilities of RMB6,420,000 and RMB29,031,000 during the year ended 31 December 2021 and the six months ended 30 June 2022, respectively, in respect of a collaboration arrangement.

(b) Changes in liabilities arising from financing activities

	Bank loans	Lease liabilities	Amount due to related parties
	RMB'000	*RMB'000*	*RMB'000*
At 1 January 2020	485,933	8,251	386,639
Changes from financing cash flows	(497,155)	(886)	227,004
New leases	–	8,171	–
Interest expense	11,222	597	–
Changes from non-financing activities	–	–	(327,355)
Exemption of payments	–	–	(1,530)
At 31 December 2020 and 1 January 2021	–	16,133	284,758
Changes from financing cash flows	(10,895)	(10,130)	2,830
New leases	–	9,499	–
Transfers	250,000	–	(250,000)
Interest expense	10,895	704	–
Changes from non-financing activities	–	–	27,651
Exemption of payments	–	(1,641)	(42,514)
Exchange realignment	–	(42)	–
At 31 December 2021 and 1 January 2022	250,000	14,523	22,725
Changes from financing cash flows	(4,678)	(5,847)	–
New leases	–	2,272	–
Interest expense	6,358	264	–
Changes from non-financing activities	–	–	(17,901)
Exchange realignment	–	91	–
At 30 June 2022	251,680	11,303	4,824

	Bank loans	Lease liabilities	Amount due to related parties
	RMB'000	*RMB'000*	*RMB'000*
At 1 January 2021	–	16,133	284,758
Changes from financing cash flows (unaudited)	(4,895)	(877)	2,830
New leases (unaudited)	–	9,499	–
Transfers (unaudited)	250,000	–	(250,000)
Interest expense (unaudited)	5,189	386	–
Changes from non-financing activities (unaudited)	–	–	31,473
Exchange realignment (unaudited)	–	11	–
At 30 June 2021 (unaudited)	250,294	25,152	69,061

(c) Total cash outflow for leases

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Within operating activities	8,295	651	167	1,076
Within financing activities	886	10,130	877	5,847
	9,181	10,781	1,044	6,923

29. COMMITMENTS

The Group had capital commitments for the acquisition of property, plant and equipment with amounts of RMB13,256,000, RMB109,034,000 and RMB182,898,000 at the end of each of the Relevant Periods.

30. RELATED PARTY TRANSACTIONS

The Group's principal related parties are as follows:

Name	Relationship with the Company
Shandong Luye	Shareholder
Mr. Liu Dian Bo	Director of Shandong Luye
Yantai Luye Pharmaceutical Holdings Co., Ltd. ("**Yantai Luye**")	Shareholder of Shandong Luye
Nanjing Luye Pharmaceutical Co., Ltd. ("**Nanjing Luye**")	Controlled by Shandong Luye
Yantai Luye Drugs Trading Co., Ltd. ("**Luye Trading**")	Controlled by Shandong Luye
Shandong International Biotechnology Development Co., Ltd. ("**Biotech Park Development**")	Controlled by Mr. Liu Dian Bo
Luye Investment Group Co., Ltd. ("**LIG**")	Controlled by Mr. Liu Dian Bo
Geneleap Biotech LLC (formerly known as "Luye Boston Research & Development LLC") ("**Luye Boston**")*	Controlled by Mr. Liu Dian Bo
Yantai Yunyue Winery Management Co., Ltd. ("**Yunyue Winery**")	Controlled by Mr. Liu Dian Bo
Yantai Cellzone Medical Diagnostics Center Co., Ltd. ("**Yantai Cellzone**")	Controlled by Mr. Liu Dian Bo

* As at 30 June 2022, Luye Boston has ceased to be a related party of the Group. The outstanding balances with the entity are not disclosed as balances with related parties in note (c) below and the transaction amounts with the entity for the Relevant Periods disclosed in note (a) only covered the periods when the entity was a related party.

(a) The Group had the following transactions with related parties during the Relevant Periods and the six months ended 30 June 2021:

		Year ended 31 December		Six months ended 30 June	
		2020	2021	2021	2022
	Notes	*RMB'000*	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Receipt of repayment from:					
LIG	*(i)*	112,458	–	–	–
Interest income from:					
LIG	*(i)*	1,164	–	–	–
Sales of goods to:					
Luye Trading	*(ii)*	–	–	–	99
Lease and property management services from:					
Shandong Luye	*(iii)*	11,657	164	–	196
Biotech Park Development	*(iii)*	340	–	–	247
Testing services from:					
Shandong Luye	*(iii)*	697	663	424	39
Research and development services from:					
Yantai Cellzone	*(iii)*	–	–	–	1,164
EHS management services from:					
Shandong Luye	*(iii)*	119	331	124	611
Operation services from:					
Nanjing Luye	*(iii)*	–	925	473	546
Facilities maintenance services from:					
Nanjing Luye	*(iii)*	–	686	686	–
Accommodation services from:					
Yunyue Winery	*(iii)*	–	370	111	44
Purchase of materials from:					
Shandong Luye	*(iii)*	32,451	2,000	1,859	–
Purchases of property, plant and equipment from:					
Shandong Luye	*(iii)*	–	25,866	25,866	–
Nanjing Luye	*(iii)*	–	16,320	16,311	–
Payments on behalf by:					
Shandong Luye	*(iv)*	5,540	12,783	5,171	8,279
Biotech Park Development	*(iv)*	2,013	1,908	1,165	904
Luye Boston	*(iv)*	–	2,431	2,317	111
Yantai Luye	*(iv)*	–	–	–	52
Repayments to:					
Shandong Luye	*(iv)*	–	4,759	–	7,770
Biotech Park Development	*(iv)*	2,256	2,358	1,319	771
Luye Boston	*(iv)*	–	2,400	1,984	104
Advances from:					
Shandong Luye	*(iv)*	886,082	2,380	2,380	–
Repayment of advances from:					
Shandong Luye	*(iv)*	659,078	229,834	229,834	–

Notes:

(i) The loans were unsecured, bore interest at rates of 4.35% to 6.18% per annum and repayable on demand or with a repayment term of six months.

(ii) The transaction price was determined on normal commercial terms, negotiated on arm's length basis, and on similar basis as the Group conducted businesses with major customers.

(iii) The transaction prices were determined on terms mutually agreed between the parties with reference to the actual cost and fees for similar transactions in the market.

(iv) The payments on behalf and advances were unsecured, interest-free and repayable on demand.

(b) Other transactions with related parties:

(i) As at 31 December 2020, LIG, Biotech Park Development and the Company entered into a debt waiver agreement, pursuant to which LIG transferred its debt to Biotech Park Development, and Biotech Park Development waived the remaining right of credit amounting to approximately RMB1,530,000 to the Company. The amount was credited to the Company's other reserves.

(ii) As at 30 December 2021, Shandong Luye and the Company entered into a debt waiver agreement, pursuant to which the Company's other payables to Shandong Luye amounting to approximately RMB44,155,000 were exempted. The amount was credited to the Company's other reserves.

(iii) As at 31 December 2021 and 30 June 2022, Shandong Luye and Yantai Luye have guaranteed the Group's bank loans amounting to RMB250,000,000 and RMB250,000,000, respectively, as disclosed in note 22 to the Historical Financial Information.

(c) Outstanding balances with related parties:

Group

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Notes payable:			
Shandong Luye*	–	15,740	–
Due to related parties:			
Shandong Luye**	283,562	2,378	4,068
Biotech Park Development***	1,196	222	158
Nanjing Luye****	–	20,094	546
Luye Boston*****	–	31	–
Yantai Luye*****	–	–	52
	284,758	22,725	4,824
Lease liabilities:			
Shandong Luye	6,305	3,181	2,411
Biotech Park Development	7,706	5,620	7,246
Nanjing Luye	2,122	2,186	725
Luye Boston	–	3,536	–
	16,133	14,523	10,382

* As at the end of the Relevant Periods, nil, RMB5,190,000 and nil of the balances were trade in nature, and nil, RMB10,550,000 and nil were non-trade in nature.

** As at the end of the Relevant Periods, RMB49,738,000, RMB148,000 and RMB474,000 of the balances were trade in nature, and RMB233,824,000, RMB2,230,000 and RMB3,594,000 were non-trade in nature.

*** As at the end of the Relevant Periods, RMB524,000, nil and nil of the balances were trade in nature, and RMB672,000, RMB222,000 and RMB158,000 were non-trade in nature.

**** The balance was trade in nature.

***** The balance was non-trade in nature.

Other outstanding balances with related parties were all trade in nature.

The balances with related parties except for lease liabilities are unsecured, interest-free and have no fixed terms of repayment.

The outstanding non-trade balances with related parties are expected to be settled in full prior to the **[REDACTED]** of the Company.

Company

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Due from a subsidiary:			
Boan Nanjing*	3,800	34,904	42,337
Notes payable:			
Shandong Luye**	–	15,740	–
Due to a subsidiary:			
Boan Singapore*	–	–	4,195
Due to related parties:			
Shandong Luye***	283,562	2,378	4,068
Biotech Park Development****	1,196	222	158
Yantai Luye*	–	–	52
	284,758	2,600	4,278
Lease liabilities:			
Shandong Luye	6,305	3,181	2,411
Biotech Park Development	7,706	5,620	7,246
	14,011	8,801	9,657

* The balance was non-trade in nature.

** As at the end of the Relevant Periods, nil, RMB5,190,000 and nil of the balances were trade in nature, and nil, RMB10,550,000 and nil were non-trade in nature.

*** As at the end of the Relevant Periods, RMB49,738,000, RMB148,000 and RMB474,000 of the balances were trade in nature, and RMB233,824,000, RMB2,230,000 and RMB3,594,000 were non-trade in nature.

**** As at the end of the Relevant Periods, RMB524,000, nil and nil of the balances were trade in nature, and RMB672,000, RMB222,000 and RMB158,000 were non-trade in nature.

Other outstanding balances with related parties were all trade in nature.

The balances with related parties except for lease liabilities are unsecured, interest-free and have no fixed terms of repayment.

(d) Compensation of key management personnel of the Group:

	Year ended 31 December		Six months ended 30 June	
	2020	2021	2021	2022
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Salaries, bonuses, allowances and benefits in kind	2,476	9,793	6,383	6,742
Pension scheme contributions	43	416	275	327
Share-based payment expense	–	13,572	5,234	6,729
Total compensation paid to key management personnel	2,519	23,781	11,892	13,798

Further details of directors', supervisors' and chief executive's remuneration are included in note 8 to the Historical Financial Information.

31. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

Group

Financial assets

As at 31 December 2020

	Financial assets at fair value through other comprehensive income	Financial assets at amortised cost	Total
	RMB'000	*RMB'000*	*RMB'000*
Notes receivable	700	–	700
Cash and cash equivalents	–	3,629	3,629
	700	3,629	4,329

As at 31 December 2021

	Financial assets at fair value through other comprehensive income	Financial assets at amortised cost	Total
	RMB'000	*RMB'000*	*RMB'000*
Trade receivables	–	78,057	78,057
Notes receivable	29,210	–	29,210
Financial assets included in prepayments, other receivables and other assets	–	2,264	2,264
Pledged deposits	–	44,853	44,853
Time deposits over three months	–	81,859	81,859
Cash and cash equivalents	–	531,703	531,703
	29,210	738,736	767,946

As at 30 June 2022

	Financial assets at fair value through other comprehensive income	Financial assets at amortised cost	Total
	RMB'000	*RMB'000*	*RMB'000*
Trade receivables	–	109,822	109,822
Notes receivable	29,208	–	29,208
Financial assets included in prepayments, other receivables and other assets	–	5	5
Pledged deposits	–	2,188	2,188
Time deposits over three months	–	100,000	100,000
Cash and cash equivalents	–	312,241	312,241
	29,208	524,256	553,464

Financial liabilities at amortised cost

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Lease liabilities	16,133	14,523	11,303
Trade and notes payable	91,585	138,714	120,539
Financial liabilities included in other payables and accruals	5,538	50,456	115,971
Interest-bearing bank loans	–	250,000	251,680
Due to related parties	284,758	22,725	4,824
	398,014	476,418	504,317

Company

Financial assets

As at 31 December 2020

	Financial assets at fair value through other comprehensive income	**Financial assets at amortised cost**	**Total**
	RMB'000	*RMB'000*	*RMB'000*
Notes receivable	700	–	700
Due from a subsidiary	–	3,800	3,800
Cash and cash equivalents	–	1,915	1,915
	700	5,715	6,415

As at 31 December 2021

	Financial assets at fair value through other comprehensive income	**Financial assets at amortised cost**	**Total**
	RMB'000	*RMB'000*	*RMB'000*
Trade receivables	–	78,057	78,057
Notes receivable	29,210	–	29,210
Financial assets included in prepayments, other receivables and other assets	–	2,264	2,264
Due from a subsidiary	–	34,904	34,904
Pledged deposits	–	44,853	44,853
Time deposits over three months	–	81,859	81,859
Cash and cash equivalents	–	503,016	503,016
	29,210	744,953	774,163

As at 30 June 2022

	Financial assets at fair value through other comprehensive income	Financial assets at amortised cost	Total
	RMB'000	*RMB'000*	*RMB'000*
Trade receivables	–	109,822	109,822
Notes receivable	29,208	–	29,208
Financial assets included in prepayments, other receivables and other assets	–	5	5
Due from a subsidiary	–	42,337	42,337
Pledged deposits	–	2,188	2,188
Time deposits over three months	–	100,000	100,000
Cash and cash equivalents	–	298,913	298,913
	29,208	553,265	582,473

Financial liabilities at amortised cost

	As at 31 December		As at 30 June
	2020	2021	2022
	RMB'000	*RMB'000*	*RMB'000*
Lease liabilities	14,011	8,801	9,657
Trade and notes payable	90,368	137,677	120,084
Financial liabilities included in other payables and accruals	5,522	49,389	115,863
Interest-bearing bank loans	–	250,000	251,680
Due to a subsidiary	–	–	4,195
Due to related parties	284,758	2,600	4,278
	394,659	448,467	505,757

32. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of cash and cash equivalents, time deposits over three months, pledged deposits, trade receivables, financial assets included in prepayments, other receivables and other assets, trade and notes payable, financial liabilities included in other payables and accruals, amounts due to related parties and current portion of interest-bearing bank loans and lease liabilities approximate to their carrying amounts largely due to the short term maturities of these instruments.

The Group's finance department headed by the financial manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance manager reports directly to the chief financial officer and the audit committee. At each reporting date, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the chief financial officer.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair values of the non-current portion of interest-bearing bank loans and lease liabilities have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities. The changes in fair value as a result of the Group's own non-performance risk were assessed to be insignificant.

The fair values of the notes receivable classified as debt investments at fair value through other comprehensive income have been calculated by discounting the expected future cash flows, which are the par values of the notes receivable. In addition, the notes receivable will mature within twelve months, and thus, their fair values approximate to their carrying values.

The following tables illustrate the fair value measurement hierarchy of the Group's financial instruments:

Assets measured at fair value:

As at 31 December 2020

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	**Significant observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Notes receivable	–	700	–	700

As at 31 December 2021

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	**Significant observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Notes receivable	–	29,210	–	29,210

As at 30 June 2022

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	**Significant observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Notes receivable	–	29,208	–	29,208

The Group did not have any financial liabilities measured at fair value as at the end of each of the Relevant Periods.

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

Liabilities for which fair values are disclosed:

As at 31 December 2021

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Interest-bearing bank loans	–	250,000	–	250,000

As at 30 June 2022

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Interest-bearing bank loans	–	245,000	–	245,000

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial instruments comprise bank loans and cash and short term deposits. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as trade receivables and trade payables, which arise directly from its operations.

The main risks arising from the Group's financial instruments are interest rate risk, foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

Interest rate risk

The Group's exposure to the risk of changes in market interest rates relates primarily to the Group's interest-bearing bank loans with a floating interest rate. The Group mitigates the risk by monitoring closely the movements in interest rates and reviewing its banking facilities regularly. The Group has not used any interest rate swap to hedge its exposure to interest rate risk.

As at 31 December 2021 and 30 June 2022, if the interest rates on bank loans had been 50 basis points higher/lower, which was considered reasonably possible by management, with all other variables held constant, the loss before tax for the year/period would have increased/decreased by RMB279,000 and RMB235,000, respectively, as a result of higher/lower interest expenses on bank loans.

Foreign currency risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. The Group has currency exposures mainly arising from cash at banks denominated in US$. At present, the Group does not intend to seek to hedge its exposure to foreign exchange fluctuations. The Group constantly monitors the economic situation and the Group's foreign exchange risk profile and will consider appropriate hedging measures in the future should the need arise.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rates, with all other variables held constant, of the Group's loss before tax and equity (due to changes in the fair value of monetary assets and liabilities).

	Increase/ (decrease) in rate of foreign currency	Decrease/ (increase) in loss before tax	Increase/ (decrease) in equity
	RMB'000	*RMB'000*	*RMB'000*
31 December 2020			
If the RMB weakens against the US$	5	–	–
If the RMB strengthens against the US$	(5)	–	–
31 December 2021			
If the RMB weakens against the US$	5	12,096	13,704
If the RMB strengthens against the US$	(5)	(12,096)	(13,704)
30 June 2022			
If the RMB weakens against the US$	5	702	2,029
If the RMB strengthens against the US$	(5)	(702)	(2,029)

Credit risk

The Group trades only with recognised and creditworthy third parties. It is the Group's policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group's exposure to bad debts is not significant.

Since the Group trades only with recognised and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty, by geographical region. There are no significant concentrations of credit risk within the Group as the customer bases of the Group's trade receivables are widely dispersed with different customers.

Maximum exposure and year-end staging

The table below shows the credit quality and the maximum exposure to credit risk based on the Group's credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at the end of each of the Relevant Periods. The amounts presented are gross carrying amounts for financial assets.

31 December 2020

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Notes receivables	700	–	–	–	700
Cash and cash equivalents					
– Not yet past due	3,629	–	–	–	3,629
	4,329	–	–	–	4,329

31 December 2021

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Trade receivables	–	–	–	78,057	78,057
Notes receivables	29,210	–	–	–	29,210
Financial assets included in prepayments, other receivables and other assets					
– Normal*	2,264	–	–	–	2,264
Pledged deposits					
– Not yet past due	44,853	–	–	–	44,853
Time deposits over three months					
– Not yet past due	81,859	–	–	–	81,859
Cash and cash equivalents					
– Not yet past due	531,703	–	–	–	531,703
	689,889	–	–	78,057	767,946

30 June 2022

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Trade receivables	–	–	–	109,848	109,848
Notes receivables	29,208	–	–	–	29,208
Financial assets included in prepayments, other receivables and other assets					
– Normal*	5	–	–	–	5
Pledged deposits					
– Not yet past due	2,188	–	–	–	2,188
Time deposits over three months					
– Not yet past due	100,000	–	–	–	100,000
Cash and cash equivalents					
– Not yet past due	312,241	–	–	–	312,241
	443,642	–	–	109,848	553,490

* The credit quality of financial assets included in prepayments, other receivables and other assets are considered to be ''normal'' when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be "doubtful".

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations of cash flows.

The Group's objective is to maintain a balance between continuity of funding and flexibility through the use of interest-bearing bank loans and lease liabilities.

The maturity profile of the Group's financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

Group

	31 December 2020				
	On demand	Less than 3 months	3 to less than 12 months	1 to 5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Lease liabilities	3,468	1,779	2,879	8,825	16,951
Trade and notes payable	8,483	83,102	–	–	91,585
Financial liabilities included in other payables and accruals	5,538	–	–	–	5,538
Due to related parties	284,758	–	–	–	284,758
	302,247	84,881	2,879	8,825	398,832

	31 December 2021				
	On demand	Less than 3 months	3 to less than 12 months	1 to 5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Lease liabilities	2,006	3,333	5,014	4,572	14,925
Trade and notes payable	18,676	95,895	24,143	–	138,714
Financial liabilities included in other payables and accruals	50,456	–	–	–	50,456
Interest-bearing bank loans	–	2,897	18,698	267,767	289,362
Due to related parties	22,725	–	–	–	22,725
	93,863	102,125	47,855	272,339	516,182

			30 June 2022		
			3 to less		
	On	Less than	than	1 to 5	
	demand	3 months	12 months	years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Lease liabilities	3,051	2,112	5,311	1,537	12,011
Trade and notes payable	20,462	98,322	1,755	–	120,539
Financial liabilities included in other payables and accruals	115,971	–	–	–	115,971
Interest-bearing bank loans	–	4,114	33,408	243,050	280,572
Due to related parties	4,824	–	–	–	4,824
	144,308	104,548	40,474	244,587	533,917

Company

			31 December 2020		
			3 to less		
	On	Less than	than	1 to	
	demand	3 months	12 months	5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Lease liabilities	2,729	1,779	2,140	8,086	14,734
Trade and notes payable	8,483	81,885	–	–	90,368
Financial liabilities included in other payables and accruals	5,522	–	–	–	5,522
Due to related parties	284,758	–	–	–	284,758
	301,492	83,664	2,140	8,086	395,382

			31 December 2021		
			3 to less		
	On	Less than	than	1 to	
	demand	3 months	12 months	5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Lease liabilities	–	2,048	2,524	4,572	9,144
Trade and notes payable	18,631	94,903	24,143	–	137,677
Financial liabilities included in other payables and accruals	49,389	–	–	–	49,389
Interest-bearing bank loans	–	2,897	18,698	267,767	289,362
Due to related parties	2,600	–	–	–	2,600
	70,620	99,848	45,365	272,339	488,172

	30 June 2022				
	On demand	Less than 3 months	3 to less than 12 months	1 to 5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Lease liabilities	2,590	1,190	4,572	1,537	9,889
Trade and notes payable	20,446	97,883	1,755	–	120,084
Financial liabilities included in other payables and accruals	115,863	–	–	–	115,863
Interest-bearing bank loans	–	4,114	33,408	243,050	280,572
Due to a subsidiary	4,195	–	–	–	4,195
Due to related parties	4,278	–	–	–	4,278
	147,372	103,187	39,735	244,587	534,881

Capital management

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital as at the end of each of the Relevant Periods.

The Group monitors capital using a gearing ratio, which is net debt divided by capital. Net debt includes interest-bearing bank loans, less cash and cash equivalents. Capital represents equity attributable to the owners of the parent. No gearing ratio was present since cash and cash equivalents exceeded the interest-bearing bank loans as at the end of each of the Relevant Periods.

34. EVENT AFTER THE RELEVANT PERIODS

There were no other significant events that required additional disclosure or adjustments occurred after the end of the Relevant Periods.

35. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or its subsidiary in respect of any period subsequent to 30 June 2022.

The following information does not form part of the Accountants' Report from Ernst & Young, Certified Public Accountants, Hong Kong, the Company's reporting accountants, as set out in Appendix I to this document, and is included for information purposes only. The unaudited pro forma financial information should be read in conjunction with "Financial Information" and the Accountants' report set out in Appendix I to this document.

A. UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited pro forma statement of adjusted consolidated net tangible assets of the Group prepared in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited and with reference to Accounting Guideline 7 *Preparation of Pro Forma Financial Information for inclusion in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the **[REDACTED]** on the unaudited consolidated net tangible assets of the Group attributable to owners of the Company as at 30 June 2022 as if the **[REDACTED]** had taken place on 30 June 2022.

The unaudited pro forma statement of adjusted consolidated net tangible assets of the Group has been prepared for illustrative purposes only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group had the **[REDACTED]** been completed as at 30 June 2022 or at any future date.

	Consolidated net tangible assets attributable to owners of the Company as at 30 June 2022 *RMB'000* *(Note 1)*	**Estimated [REDACTED] from the [REDACTED]** *RMB'000* *(Note 2)*	**Unaudited pro forma adjusted consolidated net tangible assets attributable to owners of the Company as at 30 June 2022** *RMB'000*	**Unaudited pro forma adjusted consolidated net tangible assets attributable to owners of the Company per Share as 30 June 2022** *RMB* *(Note 3)*	**Unaudited pro forma adjusted consolidated net tangible assets attributable to owners of the Company per Share as 30 June 2022** *(HK$ equivalent)* *(Note 4)*
Based on an **[REDACTED]** of HK$**[REDACTED]** per Share	755,340	**[REDACTED]**	**[REDACTED]**	**[REDACTED]**	**[REDACTED]**
Based on an **[REDACTED]** of HK$**[REDACTED]** per Share	755,340	**[REDACTED]**	**[REDACTED]**	**[REDACTED]**	**[REDACTED]**

Notes:

1. The consolidated net tangible assets attributable to owners of the Company as at 30 June 2022 is arrived at after deducting intangible assets of RMB653,210,000 from the consolidated net assets attributable to owners of the Company of RMB1,408,550,000 as at 30 June 2022, as shown in the Accountants' Report set out in Appendix I to this document.

2. The estimated [**REDACTED**] from the [**REDACTED**] are calculated based on estimated [**REDACTED**] of HK$[**REDACTED**] or HK$[**REDACTED**] per Share after deduction of the [**REDACTED**] fees and other related expenses payable by the Company (excluding [**REDACTED**] expenses of RMB[**REDACTED**] which have been charged to profit or loss during the Track Record Period) and do not take into account any Shares which may be issued upon exercise of the [**REDACTED**].

3. The unaudited pro forma adjusted consolidated net tangible assets attributable to owners of the Company per Share are calculated based on [**REDACTED**] H Shares in issue immediately following the completion of the [**REDACTED**] without taking into account any Shares which may be issued upon exercise of the [**REDACTED**].

4. The unaudited pro forma adjusted consolidated net tangible assets attributable to owners of the Company per Share are converted into Hong Kong dollars at an exchange rate of RMB1.00 to HK$1.1010.

5. No adjustment has been made to reflect any trading results or open transactions of the Group entered into subsequent to 30 June 2022.

The following is the text of a report, prepared for the purpose of incorporation in this document, received from the reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong, in respect of the unaudited pro forma financial information.

B. INDEPENDENT REPORTING ACCOUNTANTS' ASSURANCE REPORT ON THE COMPILATION OF PRO FORMA FINANCIAL INFORMATION

[To insert the firm's letterhead]

To the Directors of Shandong Boan Biotechnology Co., Ltd.

We have completed our assurance engagement to report on the compilation of pro forma financial information of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") and its subsidiaries (hereinafter collectively referred to as the "**Group**") by the directors of the Company (the "**Directors**") for illustrative purposes only. The pro forma financial information consists of the pro forma consolidated net tangible assets as at 30 June 2022, and related notes as set out on pages II-1 to II-2 of the document dated [date] issued by the Company (the "**Pro Forma Financial Information**"). The applicable criteria on the basis of which the Directors have compiled the Pro Forma Financial Information are described in Appendix II (A).

The Pro Forma Financial Information has been compiled by the Directors to illustrate the impact of the [**REDACTED**] of shares of the Company on the Group's financial position as at 30 June 2022 as if the transaction had taken place at 30 June 2022. As part of this process, information about the Group's financial position has been extracted by the Directors from the Group's financial statements for the six months ended 30 June 2022, on which an accountants' report has been published.

Directors' responsibility for the Pro Forma Financial Information

The Directors are responsible for compiling the Pro Forma Financial Information in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and with reference to Accounting Guideline ("**AG**") 7 *Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (the "**HKICPA**").

Our independence and quality control

We have complied with the independence and other ethical requirements of the *Code of Ethics for Professional Accountants* issued by the HKICPA, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies Hong Kong Standard on Quality Control 1 *Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and Other Assurance and Related Services Engagements*, and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Reporting accountants' responsibilities

Our responsibility is to express an opinion, as required by paragraph 4.29(7) of the Listing Rules, on the Pro Forma Financial Information and to report our opinion to you. We do not accept any responsibility for any reports previously given by us on any financial information used in the compilation of the Pro Forma Financial Information beyond that owed to those to whom those reports were addressed by us at the dates of their issue.

We conducted our engagement in accordance with Hong Kong Standard on Assurance Engagements 3420 *Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus* issued by the HKICPA. This standard requires that the reporting accountants plan and perform procedures to obtain reasonable assurance about whether the Directors have compiled the Pro Forma Financial Information in accordance with paragraph 4.29 of the Listing Rules and with reference to AG 7 issued by the HKICPA.

For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the Pro Forma Financial Information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the Pro Forma Financial Information.

The purpose of the Pro Forma Financial Information included in the document is solely to illustrate the impact of the [**REDACTED**] of shares of the Company on unadjusted financial information of the Group as if the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the transaction would have been as presented.

A reasonable assurance engagement to report on whether the Pro Forma Financial Information has been properly compiled on the basis of the applicable criteria involves performing procedures to assess whether the applicable criteria used by the Directors in the compilation of the Pro Forma Financial Information provide a reasonable basis for presenting the significant effects directly attributable to the transaction, and to obtain sufficient appropriate evidence about whether:

- the related pro forma adjustments give appropriate effect to those criteria; and
- the Pro Forma Financial Information reflects the proper application of those adjustments to the unadjusted financial information.

The procedures selected depend on the reporting accountants' judgment, having regard to the reporting accountants' understanding of the nature of the Group, the transaction in respect of which the Pro Forma Financial Information has been compiled, and other relevant engagement circumstances.

The engagement also involves evaluating the overall presentation of the Pro Forma Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion:

(a) the Pro Forma Financial Information has been properly compiled on the basis stated;

(b) such basis is consistent with the accounting policies of the Group; and

(c) the adjustments are appropriate for the purpose of the Pro Forma Financial Information as disclosed pursuant to paragraph 4.29(1) of the Listing Rules.

[●]
Certified Public Accountants

Hong Kong
[date]

THE PRC TAXATION

Taxation on Dividends

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得税法》), which was latest amended on August 31, 2018 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得税法實施條例》), which was latest amended on December 18, 2018 (hereinafter collectively referred to as the "**IIT Law**"), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty.

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《〈內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排〉第五議定書》) issued by the State Administration of Taxation (the "**SAT**"), which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the SAT on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家税務總局關於執行税收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Enterprise Investors

In accordance with the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》) issued by NPC on March 16, 2007, implemented on January 1, 2008 and subsequently amended on February 24, 2017 and December 29, 2018 and the Implementation Provisions of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法實施條例》) issued by the State Council on December 6, 2007, came into effect

on January 1, 2008 and amended in 2019 (hereinafter collectively referred to as the "**EIT Law**"), a nonresident enterprise is generally subject to a 10% corporate income tax on PRC-sourced income (including dividends received from a PRC resident enterprise), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for nonresident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the nonresident enterprise when such payment is made or due.

The Circular of the SAT on Issues Relating to the Withholding and Remitting of Corporate Income Tax by PRC Resident Enterprises on Dividends Distributed to Overseas Non-Resident Enterprise Shareholders of H Shares (《國家税務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得税有關問題的通知》) (Guo Shui Han [2008] No. 897), which was issued and implemented by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends of 2008 and onwards that it distributes to overseas nonresident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Corporate Income Tax on Dividends Derived by Nonresident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得税問題的批覆》) (Guo Shui Han [2009] No. 394), which was issued by the SAT and implemented on July 24, 2009, further provides that any PRC-resident enterprise listed on overseas stock exchanges must withhold and remit corporate income tax at a rate of 10% on dividends of 2008 and onwards that it distributes to nonresident enterprises. Such tax rates may be further modified pursuant to the tax treaty or agreement that China has entered into with the relevant jurisdictions, where applicable.

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《〈內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排〉第五議定書》) issued by the SAT, which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the SAT on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家税務總局關於執行税收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC are entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《關於全面推開營業税改徵增值税試點的通知》) (Cai Shui [2016] No. 36) (hereinafter referred to as "**Notice 36**"), which was implemented on May 1, 2016, entities and individuals engaged in the services sale in the PRC are subject to Value-added Tax (hereinafter referred to as "**VAT**") and "engaged in the services sale in the PRC" means that the seller or buyer of the taxable services is located in the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT.

According to these regulations, if the holder is a nonresident individual, the PRC VAT is exempted from the sale or disposal of H shares; if the holder is a nonresident enterprise and the H-share buyer is an individual or entity located outside China, the holder is not necessarily required to pay the PRC VAT, but if the H-share buyer is an individual or entity located in China, the holder may be required to pay the PRC VAT.

However, in view of no clear regulations, whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares, there is still uncertainty in the interpretation and application of the above provisions.

At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge (hereinafter collectively referred to as "**Local Additional Tax**"), which shall be usually subject to 12% of the VAT payable (if any).

Income tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular of the Ministry of Finance and the SAT on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《財政部、國家税務總局關於個人轉讓股票所得繼續暫免徵收個人所得税的通知》) (Cai Shui Zi [1998] No. 61) issued by the Ministry of Finance (the "**MOF**") and the SAT on March 30, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. The SAT has not expressly stated whether it will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended Individual Income Tax Law.

However, on December 31, 2009, the MOF, the SAT and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得税有關問題的通知》) (Cai Shui [2009] No. 167), which came into effect on January 1, 2010, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得税有關問題的補充通知》) (Cai Shui [2010] No. 70) jointly issued and implemented by such departments on November 10, 2010). As of the Latest Practicable Date, no aforesaid provisions have expressly provided that individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges.

Enterprise Investors

In accordance with the EIT Law, a nonresident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for nonresident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the nonresident enterprise when such payment is made or due. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

Pursuant to the Stamp Duty Law of the PRC (《中華人民共和國印花稅法》), which was issued on June 10, 2021 and came into effect on July 1, 2022, entities and individuals who make taxable documents and conduct securities transactions within the territory of the PRC are the taxpayers of stamp duty, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this document, no estate duty has been levied in the PRC under the PRC laws.

PRINCIPLE TAXATION OF OUR COMPANY IN THE PRC

Enterprise Income Tax

According to the EIT Law, a resident enterprise shall pay EIT on its income originating from both inside and outside PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%.

Value-added Tax

According to the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》), which was promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017 (the "**Regulations on VAT**"), and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the MOF, came into effect on December 25, 1993 and latest amended on October 28, 2011, all the taxpayers engaged in sales of goods or provision of processing, repair and maintenance labor or import of goods in China shall be subject to value-added tax. Unless specified by the Regulations on VAT, for the sales or import of goods by general taxpayers, the VAT rate shall be 17%; for provision of processing, repair and maintenance labor by taxpayers, the VAT rate shall be 17%; for export of goods by taxpayers, the VAT rate shall be nil, unless otherwise provided. According to the Circular of the Ministry of Finance and the State Administration of Foreign Exchange on Adjusting Value-added Tax Rates (《財政部、稅務總局關於調整增值稅稅率的通知》), which was issued on April 4, 2018 and came into effect on May 1, 2018, where a tax payer engages in a taxable sales activity for the value-added tax purpose or imports goods, the previous applicable reduced 17% and 11% tax rates are adjusted to be 16% and 10%, respectively. According to the Announcement on Deepening Policies in relation to Value-added Tax Reform (《關於深化增值稅改革有關政策的公告》) which was promulgated on March 20, 2019 and became effective on April 1, 2019, the VAT rates are reduced to 13% and 9%, respectively.

FOREIGN EXCHANGE

The lawful currency of the PRC is Renminbi, which is still subject to foreign exchange control and is not freely exchangeable. The SAFE, under the authorization of the People's Bank of China (the "**PBOC**"), is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The principal regulations governing foreign currency exchange in China are Regulations for Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) (the "**Foreign Exchange Control Regulations**") which was promulgated by the State Council on January 29, 1996, became effective on April 1, 1996 and was subsequently amended on January 14, 1997 and August 5, 2008 and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (Yin Fa [1996] No. 210) which was promulgated by the PBOC on June 20, 1996 and became effective on July 1, 1996. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is generally freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of SAFE or its local counterparts is obtained.

According to the Announcement on Improving the Reform of the Renminbi (《關於完善人民幣匯率形成機制改革的公告》) issued by the PBOC on July 21, 2005, the PRC began to implement a regulated and managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand with reference to a basket of currencies. The Renminbi exchange rate is no longer pegged to the US dollar. The PBOC will publish the closing price of a foreign currency such as the US dollar traded against the Renminbi in the interbank foreign exchange market on each trading day after the closing of the market, and will fix the central parity for the transaction of such foreign currency against Renminbi on the following trading day.

Since January 4, 2006, the PBOC improved the method of generating the central parity for quoting the Renminbi exchange rate by introducing an enquiry system while keeping the match-making system in the interbank foreign exchange spot market. In addition, the liquidity of the foreign exchange market was also improved by adopting a market-making system in the interbank foreign exchange market.

The Foreign Exchange Control Regulations, which became effective on August 5, 2008, have made substantial changes to the foreign exchange regulatory system of the PRC. First, the Foreign Exchange Control Regulations adopted an approach of balancing the inflow and outflow of foreign exchange fund. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administration authorities. Second, the Foreign Exchange Control Regulations improved the mechanism for determining the Renminbi exchange rate based on market supply and demand. Third, the Foreign Exchange Control Regulations enhanced the monitoring of cross-border

foreign exchange fund flows. In the event that revenues and costs in connection with international transactions suffer or may suffer a material misbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard or control measures. Fourth, the Foreign Exchange Control Regulations enhanced the supervision and administration of foreign exchange transactions and grant extensive authority to the SAFE to strengthen its supervisory and administrative ability.

According to the relevant State rules and regulations, all of the foreign exchange revenue of the PRC enterprises from the current account transactions may be retained or sold to financial institutions operating a foreign exchange sale or settlement business. Foreign exchange income from loans granted by overseas entities or from the issuance of bonds and shares is not required to be sold to, but may be deposited in foreign exchange accounts at, designated foreign exchange banks.

PRC enterprises (including foreign investment enterprises) which need foreign exchange for transactions relating to current account items may, without the approval of the SAFE, effect exchange and payment from their foreign exchange accounts or at the designated foreign exchange banks, on the strength of valid receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange may, on the strength of resolutions of the board of directors or the shareholders' meeting approving the distribution of profits, effect exchange and payment from their foreign exchange accounts or convert and pay dividends at the designated foreign exchange banks.

The Decision of the State Council on Canceling and Adjusting a Group of Administrative Approval Items and Other Matters (《國務院關於取消和調整一批行政審批項目等事項的決定》) (Guo Fa [2014] No. 50), which was issued and became effective on October 23, 2014, has canceled the administrative approval by the SAFE and its branches for matters concerning the repatriation and settlement of foreign exchange of overseas-raised funds through overseas listing.

Pursuant to the Notice on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《關於境外上市外匯管理有關問題的通知》) (Hui Fa [2014] No. 54) issued by the SAFE on December 26, 2014, a domestic issuer shall, within 15 business days from completion of its [**REDACTED**] overseas, register the overseas [**REDACTED**] with the SAFE's local branch at the place of its incorporation. The proceeds from an overseas [**REDACTED**] of a domestic issuer may be remitted to a domestic account or deposited overseas, and the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

Pursuant to the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange of Capital Accounts (《關於改革和規範資本項目結匯管理政策的通知》) (Hui Fa [2016] No. 16) issued by the SAFE on June 9, 2016, discretionary settlement of foreign exchange capital income can be settled at the banks based on the actual operating needs of the domestic companies. The proportion of discretionary settlement of foreign exchange capital income for domestic companies is temporarily set at 100%. The SAFE may timely adjust the above proportion based on international balance of payments.

TAXATION IN HONG KONG

Tax on dividends

Under the current practice of the Inland Revenue Department of Hong Kong, no tax is payable in Hong Kong in respect of dividends paid by us.

Capital gains tax and profit tax

No tax is imposed in Hong Kong in respect of capital gains from the sale of H Shares. However, trading gains from the sale of the H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving trading gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes. Trading gains from sales of H Shares effected on the Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of trading gains from sales of H Shares effected on the Stock Exchange realized by persons carrying on a business of trading or dealing in securities in Hong Kong.

Stamp duty

Hong Kong stamp duty, currently charged at the ad valorem rate of 0.13% on the higher of the consideration for or the market value of the H Shares, will be payable by the purchaser on every purchase and by the seller on every sale of Hong Kong securities, including H Shares (in other words, a total of 0.26% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK$5.00 is currently payable on any instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

Estate duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The PRC legal system

The PRC legal system is based on the PRC Constitution (《中華人民共和國憲法》) revised and took effect on March 11, 2018 (hereinafter referred to as the "**Constitution**") and is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is the signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (《中華人民共和國立法法》) which was revised and took effect on March 15, 2015 (hereinafter referred to as the "**Legislation Law**"), the NPC and its Standing Committee are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing State organs, civil, criminal and other matters. The Standing Committee of the NPC formulates and amends the laws other than those required to be enacted by the NPC and to supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws. The people's congresses of the provinces, autonomous regions and municipalities and their standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people's congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical and cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the people's congresses of the relevant provinces or autonomous regions. The standing committees of the people's congresses of the provinces or autonomous regions shall examine the legality of local regulations submitted for approval, and such approval shall be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of the relevant provinces or autonomous regions. Where, during the examination for approval of local regulations of cities divided into districts by the standing committees of the people's congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people's governments of the provinces or autonomous regions, a decision should be made to

resolve the issue. People's congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the ethnic groups in the areas concerned.

The ministries and commissions of the State Council, PBOC, the National Audit Office and the subordinate institutions with administrative functions directly under the State Council may formulate departmental rules and regulations within the permissions of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, in cases where the scope of provisions of laws or decrees needs to be further defined or additional stipulations need to be made, the Standing Committee of the NPC shall provide interpretations or make stipulations by means of decrees. Issues related to the application of laws in a court trial should be interpreted by the Supreme People's Court, issues related to the application of laws in a prosecution process of the procuratorate should be interpreted by the Supreme People's Procuratorate, and issues related to laws other than the abovementioned should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional regulations is vested in the regional legislative and administrative authorities which promulgate such regulations.

The PRC judicial system

Under the Constitution, the Law of Organization of the People's Court of the PRC (2018 Revision) (《中華人民共和國人民法院組織法(2018修訂)》) and the Law of Organization of the People's Procuratorate of the PRC (2018 Revision) (《中華人民共和國人民檢察院組織法(2018修訂)》), the people's courts of the PRC are divided into the Supreme People's Court, the local people's courts at all levels and special people's courts. The local people's courts at all levels are divided into three levels, namely, the basic people's courts, the intermediate people's courts and the higher people's courts. The basic people's courts may set up certain people's tribunals based on the status of the region, population and cases. The Supreme People's Court shall be the highest judicial organ of the state. The Supreme People's Court shall supervise the administration of justice by the local people's courts at all levels and by the special people's courts. The people's courts at a higher level shall supervise the judicial work of the people's courts at lower levels. The people's procuratorates of the PRC are divided into the Supreme People's Procuratorate, the local people's procuratorates at all levels, Military Procuratorates and other special people's

procuratorates. The Supreme People's Procuratorate shall be the highest procuratorial organ. The Supreme People's Procuratorate shall direct the work of the local people's procuratorates at all levels and of the special people's procuratorates; the people's procuratorates at higher levels shall direct the work of those at lower levels.

The people's courts employ a two-tier appellate system, i.e., judgments or rulings of the second instance at the people's courts are final. A party may appeal against the judgment or ruling of the first instance of a local people's courts. The people's procuratorate may present a protest to the people's courts at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people's procuratorate within the stipulated period, the judgments or rulings of the people's courts are final. Judgments or rulings of the second instance of the intermediate people's courts, the higher people's courts and the Supreme People's Court and those of the first instance of the Supreme People's Court are final. However, if the Supreme People's Court or the people's courts at the next higher level finds any definite errors in a legally effective final judgment or ruling of the people's court at a lower level, or if the chief judge of a people's court at any level finds any definite errors in a legally effective final judgment or ruling of such court, the case can be retried according to judicial supervision procedures.

The Civil Procedure Law of the PRC (《中華人民共和國民事訴訟法》) (hereinafter referred to as the "**PRC Civil Procedure Law**") adopted on April 9, 1991 and latest amended on December 24, 2021, prescribes the conditions for instituting a civil action, the jurisdiction of the people's court, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant's place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people's court having jurisdiction should be located at places directly connected with the disputes, such as the plaintiff's or the defendant's place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. Meanwhile, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

A foreign individual, a person without nationality, a foreign enterprise or a foreign organization is given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a people's court. Should a foreign court limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens or enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a people's court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people's court and a foreign court may request each other to serve documents, conduct investigation and collect evidence and conduct other actions on its behalf. A people's court shall not

accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people's court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people's court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment against such party.

Where a party requests for enforcement of an effective judgment or ruling made by a people's court, but the opposite party or his property is not within the territory of the People's Republic of China, the party may directly apply to the foreign court with jurisdiction for recognition and enforcement of the judgment or ruling, or the people's court may, in accordance with the provisions of international treaties to which the PRC is a signatory or in which the PRC is a participant or according to the principle of reciprocity, request for recognition and enforcement by the foreign court. Similarly, for an effective judgment or ruling made by a foreign court that requires recognition and enforcement by a people's court of the PRC, a party may directly apply to an intermediate people's court of the PRC with jurisdiction for recognition and enforcement of the judgment or ruling, or the foreign court may, in accordance with the provisions of international treaties to which its country and the PRC are signatories or in which its country is a participant or according to the principle of reciprocity, request for recognition and enforcement by the people's court, unless the people's court considers that the recognition or enforcement of such judgment or ruling would violate the basic legal principles of the PRC, its sovereignty or national security or would not be in social and public interest.

The Company Law of the PRC, the Special Regulations of the State Council on the Overseas Offering and the Listing of Shares by Joint Stock Limited Companies and the Mandatory Provisions for the Articles of Association of Companies to be Listed Overseas

The PRC Company Law was adopted by the Standing Committee of the Eighth NPC at its Fifth Session on December 29, 1993 and came into effect on July 1, 1994. It was successively amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. The newly revised the PRC Company Law has been implemented since October 26, 2018.

The Special Regulations of the State Council on the Overseas Offering and the Listing of Shares by Joint Stock Limited Companies (《國務院關於股份有限公司境外募集股份及上市的特別規定》) (hereinafter referred to as the "**Special Regulations**") were passed at the 22nd Standing Committee Meeting of the State Council on July 4, 1994 and promulgated and implemented on August 4, 1994. The Special Regulations include provisions in respect of the overseas share offering and listing of joint stock limited companies.

The Mandatory Provisions for the articles of association of Companies to be Listed Overseas (《到境外上市公司章程必備條款》) (hereinafter referred to as the "**Mandatory Provisions**") jointly promulgated by the former Securities Commission of the State Council and the former State Commission for Restructuring the Economic System on August 27, 1994 prescribe that the provisions should be incorporated in the articles of association of joint stock limited companies to be **[REDACTED]** overseas stock exchanges. Accordingly, the Mandatory Provisions have been incorporated in the articles of association. References to a "company" made in this Appendix are to a joint stock limited company established under the PRC Company Law with H Shares to be issued.

Set out below is a summary of the major provisions of the PRC Company Law, the Special Regulations and the Mandatory Provisions.

General

A "joint stock limited company" refers to a corporate legal person incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties. The liability of the company for its own debts is limited to the total amount of all assets it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

Incorporation

A company may be established by promotion or subscription. A company shall have a minimum of two but no more than 200 people as its promoters, over half of which must have a domicile within the PRC. Companies established by promotion are companies of which the registered capital is the total share capital subscribed for by all the promoters registered with the company's registration authorities. No share offering shall be made before the shares subscribed for by promoters are fully paid up. For companies established by share offering, the registered capital is the total paid-up share capital as registered with the company's registration authorities. If laws, administrative regulations and State Council decisions provide otherwise on paid-in registered capital and the minimum registered capital, a company should follow such provisions.

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters' agreements. After the promoters have confirmed the capital contribution under the articles of association, a board of directors and a supervisory board shall be elected and the board of directors shall apply for registration of establishment by filing the articles of association with the company registration authorities, and other documents as required by the law or administrative regulations.

Where companies are incorporated by subscription, not less than 35% of their total number of shares must be subscribed for by the promoters, unless otherwise provided by laws or administrative regulations. A promoter who offers shares to the public must publish a document and prepare a subscription letter to be completed, signed and sealed by subscribers, specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC law, and underwriting agreements shall be entered into. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC laws must be engaged to conduct a capital verification and furnish a certificate thereof. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription money. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued remain undersubscribed by the deadline stipulated in the document, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days after the conclusion of the inauguration meeting, the board of directors shall apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after approval of registration has been given by the relevant company registration authority for industry and commerce and a business license has been issued.

A company's promoters shall be liable for: (1) the debts and expenses incurred in the establishment process jointly and severally if the company cannot be incorporated; (2) the subscription monies paid by the subscribers together with interest at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and (3) the compensation of any damages suffered by the company in the course of its establishment as a result of the promoters' fault.

Share capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation.

The issuance of shares shall be conducted in a fair and equitable manner. Each share of the same class must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. The same price per share shall be paid by any share subscriber (whether an entity or an individual). The share offering price may be equal to or greater than the nominal value of the share, but may not be less than the nominal value.

A company must obtain the approval of CSRC to offer its shares to the overseas public. The Special Regulations and the Mandatory Provisions provide that the shares issued to foreign investors and listed overseas by a company shall be in registered form, denominated in Renminbi and subscribed for in foreign currencies. Shares issued to foreign investors (including the investors from the territories of Hong Kong, Macau and Taiwan) and listed in Hong Kong are classified as H Shares, and those shares issued to investors within the PRC, other than these regions mentioned above, are known as domestic shares. Under the Special Regulations, upon approval of CSRC, a company may agree, in the [**REDACTED**] in respect of an issue of H Shares, to retain not more than 15% of the aggregate number of such overseas [**REDACTED**] foreign shares proposed to be issued in addition to the number of [**REDACTED**] shares. The issuance of retained shares is deemed to be a part of this [**REDACTED**].

Under the PRC Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters: (1) the name and domicile of each shareholder; (2) the number of shares held by each shareholder; (3) the serial numbers of shares held by each shareholder; and (4) the date on which each shareholder acquired the shares.

Increase in share capital

Pursuant to the relevant provisions of the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

When a company launches a public issue of new shares to the public upon the approval by CSRC, a new share offering document and financial accounting report must be announced and a subscription letter must be prepared. After the new shares issued by the company has been paid up, the change must be registered with the company registration authority and a public announcement must be made accordingly. Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the establishment of a company.

Reduction of share capital

A company shall reduce its registered capital in accordance with the following procedures prescribed by the PRC Company Law: (1) the company shall prepare a balance sheet and an inventory of assets; (2) the reduction of registered capital must be approved by shareholders at general meeting; (3) the company shall notify its creditors within 10 days and publish an announcement in newspapers within 30 days from the day on which the resolution approving the reduction was passed; (4) the creditors of the company are entitled to require the company to repay its debts or provide guarantees for such debts within 30 days from receipt of the notification or within 45 days from the date of the announcement if he/she/it has not received any notification; and (5) the company must apply to the company registration authority for change in registration.

Repurchase of shares

Pursuant to the PRC Company Law, a company may not repurchase its own shares other than for the following purposes: (1) reducing its registered capital; (2) merging with other companies which hold its shares; (3) carrying out an employee stock ownership plan or equity incentive plan; (4) acquiring its shares at the request of its shareholders who vote in a shareholders' general meeting against a resolution regarding a merger and division; (5) utilizing the shares for conversion of listed corporate bonds which are convertible into shares; and (6) where it is necessary for the listed company to safeguard the value of the company and the interests of its shareholders. The acquisition by a company of its own shares on the grounds set out in item (1) to (2) above shall be approved by way of a resolution of a shareholders' general meeting; the acquisition by a company of its own shares in circumstances as set out in items (3), (5) and (6) above may be approved by way of a resolution at a board meeting with two-third or more of the directors present in accordance with the provisions of the company's articles of association or the authorization of the shareholders' general meeting.

Following the acquisition by a company of its own shares in accordance with these requirements, such shares shall be canceled within 10 days from the date of the acquisition under the circumstance in item (1); such shares shall be transferred or canceled within six months under the circumstances in items (2) or (4); the total shares held by the Company shall not exceed 10% of the total shares issued by the Company and such shares shall be transferred or canceled within three years under the circumstances in items (3), (5) or (6).

A listed company shall perform its information disclosure obligations in accordance with the provisions of the Securities Law of People's Republic of China when acquiring its own shares. The acquisition by a listed company of its own shares in circumstances as set out in items (3), (5) and (6) of this article shall be conducted through open centralized trading.

The Company shall not accept the shares of the Company as the subject of pledge.

Transfer of shares

Shares held by shareholders may be transferred legally. Pursuant to the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in other manner specified by laws and administrative regulations. Following the transfer, the company shall enter the names and addresses of the transferees into its share register. No changes of registration in the share register described above shall be effected during a period of 20 days prior to convening a shareholders' general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, unless otherwise stipulated by laws on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder. The Mandatory Provision provides that changes due to share transfer should not be made to shareholder registry within 30 days before a shareholders' general meeting or within 5 days before the record date for the purpose of determining entitlements to dividend distributions.

Pursuant to the PRC Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public issue of shares may not be transferred within one year of the date of the company's listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and changes in such shareholdings. During their terms of office, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year from the date of the company's listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

Shareholders

Under the PRC Company Law, the rights of shareholders include the rights: (1) to receive a return on assets, participate in significant decision-making and select management personnel; (2) to petition the people's court to revoke any resolution passed on a shareholders' general meeting or a meeting of the board of directors that has been convened or whose voting has been conducted in violation of the laws, regulations or the articles of association, or any resolution the contents of which is in violation of the articles of association, provided that such petition shall be submitted within 60 days of the passing of such resolution; (3) to transfer the shares of the shareholders legally; (4) to attend or appoint a proxy to attend shareholders' general meetings and exercise the voting rights; (5) to inspect the articles of association, share register, counterfoil of company debentures, minutes of shareholders' general meetings, board resolutions, resolutions of the board of supervisors and financial and accounting reports, and to make suggestions or inquiries in respect of the company's operations; (6) to receive dividends in respect of the number of shares held; (7) to participate in distribution of residual properties of the

company in proportion to their shareholdings upon the liquidation of the company; and (8) any other shareholders' rights provided for in laws, administrative regulations, other normative documents and the articles of association.

The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of subscription monies agreed to be paid in respect of the shares taken up by them and any other shareholder obligation specified in the articles of association.

Shareholders' general meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The general meeting may exercise its powers: (1) to decide on the company's operational objectives and investment plans; (2) to elect and dismiss the directors and supervisors not being representative(s) of employees and to decide on the matters relating to the remuneration of directors and supervisors; (3) to review and approve the reports of the board of directors; (4) to review and approve the reports of the board of supervisors or the reports of the supervisors; (5) to review and approve the company's annual financial budgets proposals and final accounts proposals; (6) to review and approve the company's profit distribution proposals and loss recovery proposals; (7) to decide on any increase or reduction of the company's registered capital; (8) to decide on the issue of corporate bonds; (9) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form; (10) to amend the company's articles of association; and (11) to exercise any other authority stipulated in the articles of association.

Pursuant to the PRC Company Law and the Mandatory Provisions, a shareholders' general meeting is required to be held once every year within six months after the end of the previous accounting year. An extraordinary general meeting is required to be held within two months upon the occurrence of any of the following: (1) the number of directors is less than the number required by law or less than two-thirds of the number specified in the articles of association; (2) the total outstanding losses of the company amounted to one-third of the company's total paid-in share capital; (3) shareholders individually or in aggregate holding 10% or more of the company's shares request to convene an extraordinary general meeting; (4) the board deems necessary; (5) the board of supervisors so proposes; or (6) any other circumstances as provided for in the articles of association.

A shareholders' general meeting shall be convened by the board of directors and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or is not performing his duties, a director recommended by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties, the board of supervisors shall convene and preside over the shareholders' general meeting in a timely manner. If the board of supervisors fails to

convene and preside over the shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over the shareholders' general meeting.

In accordance with the PRC Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days prior to the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. For the issuance of bearer share certificates, the time and venue of and matters to be considered at the meeting shall be announced 30 days prior to the meeting. A single shareholder who holds, or several shareholders who jointly hold, more than three percent of the shares of the company may submit an interim proposal in writing to the board of directors within 10 days before the general meeting. The board of directors shall notify other shareholders within two days upon receipt of the proposal, and submit the interim proposal to the general meeting for deliberation. The contents of the interim proposal shall fall within the scope of powers of the general meeting, and the proposal shall provide clear agenda and specific matters for a resolution is to be made. A general meeting shall not make any resolution in respect of any matter not set out in the notices. Holders of bearer share certificates who intend to attend a general meeting shall deposit their share certificates with the company during the time from five days before the meeting to the conclusion of the meeting.

Pursuant to the Official Reply of the State Council regarding Adjusting the Application of Provisions to Matters Including the Notice Period for Convention of Shareholders' Meetings by Overseas Listed Companies (《國務院關於調整適用在境外上市公司召開股東大會通知期限等事項規定的批覆》(Guo Han [2019] No. 97)), which came into effect on October 17, 2019, for those joint stock companies registered in the PRC but listed outside the PRC, the requirements for the notice period for convening a shareholders' meeting, shareholders' proposal right, and the procedures for convening a shareholders' meeting shall be collectively governed by the relevant provisions of the PRC Company Law, and no longer be governed by the provisions of Article 20 through Article 22 of the Special Regulations.

Pursuant to the PRC Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that the Company's shares held by the company are not entitled to any voting rights.

An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Pursuant to the PRC Company Law, resolutions of the general meeting must be passed by more than half of the voting rights held by shareholders present at the meeting, with the exception of resolutions relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, in each case of which must be passed by more than two-thirds of the voting rights held by the shareholders present at the meeting. Where the PRC Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company and such other matters must be approved by way of resolution of the general meeting, the board of directors shall convene a shareholders' general meeting promptly to vote on such matters. A shareholder may entrust a proxy to attend the general meeting on his/her behalf. The proxy shall present the shareholders' power of attorney to the company and exercise voting rights within the scope of authorization.

Minutes shall be prepared in respect of matters considered at the general meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Pursuant to the Mandatory Provisions, the increase or reduction of share capital, the issuance of shares of any class, warrants or other similar securities and bonds, the division, merger, dissolution and liquidation of the company, the amendments to the articles of association and any other matters, which, as resolved by way of an ordinary resolution of the general meeting, may have a material impact on the company and require adoption by way of a special resolution, must be approved through special resolutions by more than two-thirds of the voting rights held by shareholders (including his/her proxies) present at the meeting.

The Mandatory Provisions require a special resolution to be passed at the general meeting and a class meeting to be held in the event of a variation or derogation of the class rights of a shareholder class. For this purpose, holders of domestic shares and H shares are deemed to be shareholders of different classes.

Board of directors

A company shall have a board of directors, which shall consist of 5 to 19 members. Members of the board of directors may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly reelected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of director results in the number of directors being less than the quorum.

Under the PRC Company Law, the board of directors may exercise its powers:

(1) to convene shareholders' general meetings and report on its work to the shareholders' general meetings;

(2) to implement the resolutions passed by the shareholders at the shareholders' general meetings;

(3) to decide on the company's operational plans and investment proposals;

(4) to formulate proposal for the company's annual financial budgets and final accounts;

(5) to formulate the company's profit distribution proposals and loss recovery proposals;

(6) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;

(7) to formulate proposals for the merger, division or dissolution of the company or change of corporate form;

(8) to decide on the setup of the company's internal management organs;

(9) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations;

(10) to formulate the company's basic management system; and

(11) to exercise any other authority stipulated in the articles of association.

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the supervisory board. The chairman shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board of directors may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization. Meanwhile, the board of directors shall keep minutes of resolutions passed at board meetings. The minutes shall be signed by the directors present at the meeting.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company: (1) a person who is unable or has limited ability to undertake any civil liabilities; (2) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist economic order, or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence; (3) a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise; (4) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; and (5) a person who is liable for a relatively large amount of debts that are overdue.

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the company.

In addition, the Mandatory Provisions further provide other circumstances under which a person is disqualified from acting as a director of a company, including: (1) the person is under investigation by the judicial authorities after a claim has been brought for violating the criminal law, pending conclusion of the case; (2) the person is not eligible for enterprise leadership under the laws and administrative regulations; (3) the person is not a natural person; and (4) no more than five years have lapsed since the person was found guilty of violating relevant securities regulations and involved in fraud or dishonesty as adjudged by relevant regulatory authorities.

Under the PRC Company Law, the board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing, or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing, or is not performing his/her duties, a director jointly elected by more than half of the directors shall perform his/her duties.

Supervisory board

A company shall have a supervisory board composed of not less than three members. The supervisory board shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company's staff, among which the proportion of representatives of the company's staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company's staff at the supervisory board shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. The supervisory board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the supervisory board shall be elected by more than half of all the supervisors. Directors and senior management members shall not act concurrently as supervisors.

According to the Reply of the Overseas Listing Department of CSRC and the Production System Department of the State Commission for Restructuring the Economic System on Opinions Concerning the Supplement and Amendment to Articles of Association by Companies to Be Listed in Hong Kong (《中國證監會海外上市部、國家體改委生產體制司關於到香港上市公司對公司章程作補充修改的意見的函》), the chairman of the supervisory board shall be selected by more than two-thirds of all the supervisors.

The chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the chairman of the supervisory board is incapable of performing, or is not performing his/her duties, the vice chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the vice chairman of the supervisory board is incapable of performing, or is not performing his/her duties, a supervisor elected by more than half of the supervisors shall convene and preside over supervisory board meetings.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisor results in the number of supervisors being less than the quorum.

The supervisory board may exercise its powers:

(1) to review the company's financial position;

(2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or resolutions of the shareholders' general meetings;

(3) when the acts of a director or a senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts;

(4) to propose the convening of extraordinary shareholders' general meetings and to convene and preside over shareholders' general meetings when the board fails to perform the duty of convening and presiding over shareholders' general meetings under the PRC Company Law;

(5) to submit proposals to the shareholders' general meetings;

(6) to bring actions against directors and senior management personnel pursuant to the relevant provisions of the PRC Company Law; and

(7) to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The supervisory board may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

Manager and senior management

Under the relevant requirements of the PRC Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. Meanwhile, under the relevant requirements of the Mandatory Provisions, the manager, who reports to the board of directors, may exercise his/her powers:

(1) to manage the production and operation and administration of the company and arrange for the implementation of the resolutions of the board of directors;

(2) to arrange for the implementation of the company's annual operation plans and investment proposals;

(3) to formulate proposals for the establishment of the company's internal management organs;

(4) to formulate the fundamental management system of the company;

(5) to formulate the company's specific rules and regulations;

(6) to recommend the appointment or dismissal of any deputy manager and any financial officer of the company;

(7) to appoint or dismiss management personnel (other than those required to be appointed or dismissed by the board of directors); and

(8) to exercise any other authority granted by the board of directors.

Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director.

According to the PRC Company Law, senior management refers to manager, deputy manager, financial officer, secretary to the board of a listed company and other personnel as stipulated in the articles of association.

Duties of directors, supervisors, general managers and other senior management

Directors, supervisors and senior management are required under the PRC Company Law to comply with the relevant laws, administrative regulations and the articles of association, and shall be obliged to be faithful and diligent towards the Company. Directors, supervisors and management personnel are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property.

Furthermore, directors and senior management are prohibited from:

(1) misappropriating company funds;

(2) depositing company funds into accounts under their own names or the names of other individuals;

(3) loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors;

(4) entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting;

(5) using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting;

(6) accepting for their own benefit commissions from a third party for transactions conducted with the company;

(7) unauthorized divulgence of confidential information of the company; and

(8) other acts in violation of their duty of loyalty to the company.

Income generated by directors or senior management in violation of aforementioned shall be returned to the company.

A director, supervisor or senior management who contravenes law, administrative regulation or the articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. Directors and senior management shall furnish all true information and data to the supervisory board, without impeding the discharge of duties by the supervisory board or supervisors.

Where a director or senior management contravenes laws, administrative regulations or the articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate more than 1% of the company's shares consecutively for more than 180 days may request in writing that the supervisory board institute litigation at the people's court. Where the supervisory violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at the people's court on its behalf. If the supervisory board or the board of directors refuses to institute litigation after receiving this written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at the people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at the people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at the people's court.

The Special Regulations and the Mandatory Provisions provide that a company's directors, supervisors, manager and other senior management shall have duty of good faith to the company. They are required to faithfully perform their duties, to protect the interests of the company and not to use their positions in the company for their own benefits. The Mandatory Provisions contain detailed stipulations on these duties.

Finance and accounting

Under the PRC Company Law, A company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments under the State Council. At the end of each accounting year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with laws. The financial and accounting reports shall be prepared in accordance with laws, administrative regulations and the regulations of the financial departments under the State Council. The company's financial and accounting reports shall be made available for shareholders' inspection at the company within 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings shall announce its financial and accounting reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached more than 50% of the PRC company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of its own shares held by it.

The premium over the nominal value per share of the company on issue and other income as required by relevant governmental department to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

Appointment and dismissal of auditors

Pursuant to the PRC Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of data.

The Special Regulations require a company to engage an independent qualified accounting firm to audit the company's annual reports and to review and check other financial reports of the company. The accounting firm's term of office shall commence from the end of the shareholders' annual general meeting to the end of the next shareholders' annual general meeting.

Profit distribution

According to the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided. Additionally, the Special Regulations require that any dividend and other distribution to shareholders of H Shares shall be declared and calculated in RMB and paid in foreign currency. Under the Mandatory Provisions, a company shall make foreign currency payments to shareholders through receiving agents.

Amendments to the articles of association

Pursuant to PRC Company Law, the resolution of a shareholders' general meeting regarding any amendment to a company's articles of association requires affirmative votes by more than two-thirds of the votes held by shareholders attending the meeting. Pursuant to the Mandatory Provisions, the company may amend its articles of association according to the laws, administrative regulations and the articles of association. The amendment to articles of association involving content of the Mandatory Provisions will only be effective upon approval of the department in charge of company examination authorized by the State Council and approval of the securities regulatory department under by the State Council, while the amendment to articles of association involving matters of company registration must be registered with the relevant authority in accordance with laws.

Dissolution and liquidation

Under the PRC Company Law, a company shall be dissolved for any of the following reasons:

(1) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;

(2) the shareholders have resolved at a shareholders' general meeting to dissolve the company;

(3) the company shall be dissolved by reason of its merger or division;

(4) the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or

(5) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders' interests.

In the event of paragraph (1) above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph (1), (2), (4) or (5) above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' general meeting. If a liquidation committee is not established within the stipulated period, the company's creditors can apply to the people's court for setting up a liquidation committee with designated relevant personnel to conduct the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The sort out committee may exercise following powers during the liquidation:

(1) to sort out the company's assets and to prepare a balance sheet and an inventory of assets;

(2) to notify the company's creditors or publish announcements;

(3) to deal with any outstanding business related to the liquidation;

(4) to pay any overdue tax together with any tax arising during the liquidation process;

(5) to settle the company's claims and liabilities;

(6) to handle the company's remaining assets after its debts have been paid off; and

(7) to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within 10 days of its establishment, and publish an announcement in newspapers within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification.

A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.

Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people's court, the liquidation committee shall hand over the administration of the liquidation to the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' general meeting or the people's court for verification, and to the company registration authority for the cancellation of company registration, and an announcement of its termination shall be published. Members of the liquidation committee shall be faithful in the discharge of their duties and shall perform their liquidation duties in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. Members of the liquidation committee who have caused the company or its creditors to suffer from any loss due to intentional fault or gross negligence, should be liable for making compensations to the company or its creditors. In addition, liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

Overseas listing

The shares of a company shall only be listed overseas after obtaining approval from CSRC, and the listing must be arranged in accordance with procedures specified by the State Council. Pursuant to the Special Regulations, a company may issue shares to overseas investors and list its shares overseas upon approval from CSRC. Subject to approval of the company's plans to issue overseas-listed foreign shares and domestic shares by CSRC, the board of directors of the company may make arrangement to implement such plans for issuance of shares, respectively, within fifteen months from the date of approval by CSRC.

In addition, if a company fails to issue all the shares as planned in one issue, it is not allowed to issue new shares not covered by the plan. If a company needs to adjust the issue plan, the shareholders' general meeting shall adopt a resolution for the examination by the company examination and approval department authorized by the State Council and the approval by the Securities Committee of the State Council.

Loss of share certificates

A shareholder may, in accordance with the public notice procedures set out in the PRC Civil Procedure Law, apply to a people's court if his share certificate(s) in registered form is either stolen, lost or destroyed, for a declaration that such certificate(s) will no longer be valid. After the people's court declares that such certificate(s) will no longer be valid, the shareholder may apply to the company for the issue of a replacement certificate(s).

A separate procedure regarding the loss of share certificates and H Share certificates of the overseas-[**REDACTED**] foreign shareholders of the PRC is provided for in the Mandatory Provisions, details of which are set out in the articles of association.

Merger and division

Under the PRC Company Law, a merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in Newspapers within 30 days. A creditor may, within 30 days from the date of reception of the notification, or within 45 days from the date of the announcement if he has not received such notification, request the company to settle any outstanding debts or provide corresponding guarantees.

In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company. In case of a division, the company's assets shall be divided and a balance sheet and an inventory of assets shall be prepared. When a resolution regarding the company's division is approved, the company should notify all its creditors within 10 days of the date of passing such resolution and publicly announce the division in newspapers within 30 days. Unless an agreement in writing is reached with

creditors before the company's division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

Changes in the registration as a result of the merger or division shall be registered with the relevant administration authority for industry and commerce.

The PRC Securities Laws, Regulations and Regulatory Regimes

The PRC has promulgated a series of regulations that relate to the issue and trading of the Shares and disclosure of information. In October 1992, the State Council established the Securities Committee and CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities- related institutions in the PRC and administering CSRC. CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and CSRC and reformed CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) govern the application and approval procedures for public offerings of shares, issuing of and trading of shares, the acquisition of listed companies, deposit, clearing and transfer of shares, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

On December 25, 1995, the State Council promulgated the Special Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的特別規定》). These regulations principally govern the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The PRC Securities Law (《中華人民共和國證券法》) (the "**Securities Law**") took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest Securities Law was implemented on March 1, 2020. It was the first national securities law in the PRC, and is divided into 14 chapters and 226 articles comprehensively regulating activities in the PRC securities market, including the issue and trading of securities, takeovers by listed companies and the duties and responsibilities of the securities exchanges, securities companies, securities clearing institutions and securities regulatory authorities. Article 224 of the PRC Securities Law provides that domestic enterprises shall satisfy the relevant requirements of the State Council when it issues shares or lists shares outside the PRC directly or indirectly. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and CSRC.

Arbitration and enforcement of arbitral awards

The Arbitration Law of the PRC (2017 Amendment) (《中華人民共和國仲裁法(2017修正)》) (the "**PRC Arbitration Law**") was enacted by the Standing Committee of the NPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. It is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration provisions in accordance with the PRC Arbitration Law and the PRC Civil Procedure Law. Where the involved parties have agreed to settle disputes by means of arbitration, a people's court will refuse to handle a legal proceeding initiated by one of the parties at such people's court, unless the arbitration agreement has lapsed.

The Listing Rules and the Mandatory Provisions require an arbitration clause to be included in the articles of association of a company listed in Hong Kong and, the Listing Rules, also require contracts between the company and each director or supervisor shall include arbitration clauses. Pursuant to such clause, whenever a dispute or claim arises from right or obligation provided in the articles of association, the PRC Company Law or other relevant laws and administrative regulations concerning the affairs of the company between (1) a holder of overseas listed foreign shares and the company; (2) a holder of overseas listed foreign shares and a holder of domestic shares; or (3) a holder of overseas listed foreign shares and the company's directors, supervisors or other management personnel, such parties shall be required to refer such dispute or claim to arbitration at either the China International Economic and Trade Arbitration Commission ("**CIETAC**") or the Hong Kong International Arbitration Center ("**HKIAC**"). Disputes in respect of the definition of shareholder and disputes in relation to the company's shareholder registry need not be resolved by arbitration. If the party seeking arbitration elects to arbitrate the dispute or claim at the HKIAC, then either party may apply to have such arbitration conducted in Shenzhen in accordance with the securities arbitration rules of the HKIAC.

Under the PRC Arbitration Law and PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If one party fails to comply with the arbitral award, the other party to the award may apply to a people's court for its enforcement. However, the people's court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including but not limited to irregularity in the composition of the arbitration tribunal, the jurisdiction of the arbitration commission, or the making of an award on matters beyond the scope of the arbitration agreement or outside the jurisdiction of the arbitration commission).

Any party seeking to enforce an award of a foreign affairs arbitration organ of the PRC against a party who or whose property is not located within the PRC may apply to a foreign court with jurisdiction over the relevant matters for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitral body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the "**New York Convention**") passed on June 10, 1958 pursuant to a resolution passed by the Standing Committee of the NPC on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of that state. At the time of the PRC's accession to the Convention, the Standing Committee of the NPC declared that (1) the PRC will only apply the New York Convention to the recognition and enforcement of arbitral awards made in the territories of other parties based on the principle of reciprocity; and (2) the New York Convention will only apply to disputes deemed under PRC laws to be arising from contractual or non-contractual mercantile legal relations.

An arrangement for mutual enforcement of arbitral awards between Hong Kong and the Supreme People's Court of China was reached. The Supreme People's Court of China adopted the Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region on June 18, 1999, which went into effect on February 1, 2000, which was amended by the Supplemental Arrangement of the Supreme People's Court for the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region implemented in November 27, 2020 and the Supplemental Arrangement of the Supreme People's Court for the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (2021) implemented in May 19, 2021. The arrangements reflects the spirit of the New York Convention. Under the arrangements, the awards by the Mainland arbitral bodies recognized by Hong Kong may be enforced in Hong Kong and the awards by the Hong Kong arbitral bodies may also be enforced in the Mainland China. If the Mainland court finds that the enforcement of awards made by the Hong Kong arbitral bodies in the Mainland will be against public interests of the Mainland, the awards may not be enforced.

SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND PRC COMPANY LAW

The Hong Kong laws applicable to a company incorporated in Hong Kong are the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance and are supplemented by common law and the rules of equity that are applicable to Hong Kong. As a joint stock limited company established in the PRC that is seeking a [**REDACTED**] of shares on the Stock Exchange, the Company is governed by the PRC Company Law and all other rules and regulations promulgated pursuant to the PRC Company Law.

Set out below is a summary of certain material differences between Hong Kong laws applicable to a company incorporated in Hong Kong and the PRC Company Law applicable to a joint stock limited company incorporated under the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.

Incorporation of corporate

Under Hong Kong laws, a company with share capital, shall be incorporated by the Registrar of Companies in Hong Kong and the company will acquire an independent corporate existence upon its incorporation. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain provisions that restrict a member's right to transfer shares. A public company's articles of association do not contain such provisions.

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or subscription. The amended PRC Company Law which came into effect on October 26, 2018 has no provision on the minimum registered capital of joint stock companies, except that laws, administrative regulations and State Council decisions have separate provisions on paid-in registered capital and the minimum registered capital of joint stock, in which case the company should follow such provisions.

Share capital

The Companies Ordinance does not provide for authorized share capital. The share capital of a Hong Kong company would be its issued share capital. The full proceeds of a share issue will be credited to share capital and becomes a company's share capital. Under Hong Kong laws, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law provides that any increase in our registered capital must be approved by our shareholders' general meeting and the relevant PRC governmental and regulatory authorities. There are no minimum capital requirements for companies incorporated in Hong Kong.

Under the PRC Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and transfer procedures of property rights must be carried out to ensure no over-valuation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong laws.

Restrictions on shareholding and transfer of shares

Under PRC laws, our Domestic Shares, which are denominated and subscribed for in Renminbi, may only be subscribed for and traded by the government or government authorized departments, PRC legal persons, natural persons, qualified foreign institutional investors, or eligible foreign strategic investors. Overseas [**REDACTED**] shares, which are denominated in Renminbi and subscribed for in a foreign currency other than Renminbi, may only be subscribed for, and traded by investors from Hong Kong, Macau or Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors. However, qualified institutional investors and individual investors may trade Southbound Hong Kong trading Link and Northbound Shanghai trading Link (or the Northbound Shenzhen trading Link) shares via participating in Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

Under the PRC Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to the [**REDACTED**] cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited company held by its directors, supervisors and senior management transferred each year during their term of office shall not exceed 25% of the total shares they held in the company, and the shares they held in the company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after such person has left office. The articles of association may set other restrictive requirements on the transfer of the company's shares held by its directors, supervisors and senior management. There are no such restrictions on shareholdings and transfers of shares under Hong Kong laws apart from six-month lockup on the company's issue of shares and the 12-month lockup on controlling shareholders' disposal of shares.

Financial assistance for acquisition of shares

The PRC Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company's shares. However, the Mandatory Provisions contain special restrictions provisions on a company and its subsidiaries on providing aforesaid financial assistance similar to those under the Companies Ordinance.

Variation of class rights

The PRC Company Law has no special provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate separate regulations relating to other kinds of shares. The Mandatory Provisions contain elaborate provisions relating to the circumstances which are deemed to be variations of class rights and the approval procedure required to be followed in respect thereof. These provisions have been incorporated in the Articles of Association.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the approval of a special resolution of the holders of the relevant class at a separate general meeting; (ii) with the consent in writing of the holders; representing at least 75% of the total voting rights of holders of the relevant class of shares or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

Directors, senior management and supervisors

The PRC Company Law, unlike the Companies Ordinance, does not contain any requirements relating to the declaration of directors' interests in material contracts, restrictions on companies providing certain benefits to directors and guarantees in respect of directors' liability and prohibitions against compensation for loss of office without shareholders' approval. The Mandatory Provisions, however, contain certain restrictions on interested contracts and specify the circumstances under which a director may receive compensation for loss of office.

Supervisory board

Under the PRC Company Law, a joint stock limited company's directors and members of the senior management are subject to the supervision of supervisory board. There is no mandatory requirement for the establishment of supervisory board for a company incorporated in Hong Kong. The Mandatory Provisions provide that each supervisor owes a duty, in the exercise of his powers, to act in good faith and honestly in what he considers to be in the best interests of the company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

Derivative action by minority shareholders

According to Hong Kong laws, as permitted by court, shareholders may initiate a derivative action on behalf of the company against directors who have any misconduct to the company if the directors control a majority of votes at a general meeting, thereby effectively preventing a company from suing the directors in breach of their duties in its own name.

The PRC Company Law provides shareholders of a joint stock limited company with the right so that in the event where the directors and senior management violate their obligations and cause damages to a company, the shareholders individually or jointly holding more than 1% of the shares in the company for more than 180 consecutive days may request in writing the supervisory board to initiate proceedings in the people's court. In the event that the supervisory board violates their obligations and cause damages to company, the above said shareholders may send written request to the board of directors to initiate proceedings in the people's court. Upon receipt of aforesaid written request from the shareholders, if the supervisory board or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days from the date of receipt of the request, or if under urgent situations, failure of initiating immediate proceeding

may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company's interests, have the right to initiate proceedings directly to the people's court in their own name.

The Mandatory Provisions also provide further remedies against the directors, supervisors and senior management who breach their duties to the company. In addition, as a condition to the listing of shares on the Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors of the company in default.

Protection of minorities

Under Hong Kong laws, a shareholder who complains that the business of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to the court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong.

According to the PRC Company Law, in the event that the company encounters substantial difficulties in its operation and management and its continuance shall cause a significant loss to the interest of its shareholders, and where this cannot be resolved through other means, the shareholders who hold more than 10% of the total shareholders' voting rights of the company may present a petition to the People's Court for the dissolution of the company. The Mandatory Provisions, however, contains provisions that a controlling shareholder may not exercise its voting rights in a prejudicial manner to the interests of the entire or part of shareholders of a company to relieve a director or supervisor of his duty to act honestly in the best interests of the company or to approve the expropriation by a director or supervisor of the company's assets or the individual rights of other shareholders.

Notice of shareholders' general meetings

Under the PRC Company Law, notice of a shareholders' annual general meeting and an extraordinary shareholders meeting must be given to shareholders at least 20 days and 15 days before the meeting, respectively. Under the Special Regulations and the Mandatory Provisions, at least 45 days' written notice must be given to all shareholders before the meeting and shareholders who wish to attend the meeting must send their writing replies to the company at least 20 days before the date of the meeting.

For a company incorporated in Hong Kong, the notice period for an annual general meeting is at least 21 days and in any other case, at least 14 days for a limited company and at least 7 days for an unlimited company.

Quorum for shareholders' general meetings

Under the Companies Ordinance, the quorum for a general meeting must be at least two members unless the articles of association of the company otherwise provided. For companies with only one shareholder, the quorum must be one member. The PRC Company Law does not specify the quorum for a shareholders' general meeting, but the Special Regulations and the Mandatory Provisions provide that general meetings may only be convened after replies to the notice of that meeting have been received from shareholders whose shares represent at least 50% of the voting rights at least 20 days before the proposed date of the meeting, or if the replies of shareholders is not reached 50% of the voting rights, the company shall within five days notify its shareholders again by way of a public announcement and the shareholders' general meeting may be held thereafter.

Voting

Under the Companies Ordinance, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes casted by shareholders present in person, or by proxy, at a general meeting.

Under the PRC Company Law, the passing of any resolution requires more than one-half of the affirmative votes held by our shareholders present at a shareholders' meeting except in cases such as proposed amendments to our articles of association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require two-thirds of the affirmative votes cast by shareholders present at a shareholders' general meeting.

Financial disclosure

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders' annual general meeting. In addition, a joint stock limited company of which the shares are publicly issued must publish its financial report. The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors' report and directors' report, which are to be presented before the company's annual general meeting, not less than 21 days before such meeting. A joint stock limited company is required under the PRC laws to prepare its financial statements in accordance with the PRC GAAP. In addition, pursuant to the Mandatory Provisions, a company must, in addition to preparing financial statements according to the PRC GAAP, have its financial statements prepared and audited in accordance with international accounting standards or the accounting standards of the oversea place where the shares are listed and its financial statements must also contain a statement of the financial effect of the material differences (if any) from the financial statements prepared in accordance with the PRC GAAP. The lower of the after-tax profits of a specific fiscal year stated in the statements prepared based on the above-mentioned

principles shall prevail in the allocation of such profits. The company shall publish its financial reports twice in each accounting year. An interim financial report shall be published within 60 days after the end of the first six months of each accounting year, while an annual financial report shall be published within 120 days after the end of each accounting year.

The Special Regulations require that there should not be any contradiction between the information disclosed within and outside the PRC and that, to the extent that there are differences in the information disclosed in accordance with the relevant PRC and overseas laws, regulations and requirements of the relevant stock exchanges, such differences should also be disclosed simultaneously.

Information on directors and shareholders

The PRC Company Law gives shareholders the right to inspect the company's articles of association, minutes of the shareholders' general meetings, share register, counterfoil of company debentures, resolutions of board meetings, resolutions of the board of supervisors and financial and accounting reports, which is similar to the shareholders' rights of Hong Kong companies under Hong Kong laws.

Receiving agent

Under the PRC Company Law and Hong Kong laws, dividends once declared are debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under PRC laws this limitation period is three years. The Mandatory Provisions require the relevant company to appoint a trust company registered under the Hong Kong Trustee Ordinance (Chapter 29 of the Laws of Hong Kong) as a receiving agent to receive on behalf of holders of shares dividends declared and all other monies owed by the company in respect of its shares.

Corporate reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its shareholders under Section 673 and Section 674 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders' approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance.

Under PRC laws, merger, division, dissolution or change the form of a joint stock limited company has to be approved by shareholders in general meeting.

Dispute arbitration

In Hong Kong, disputes between shareholders on the one hand, and a company incorporated in Hong Kong or its directors on the other hand, may be resolved through legal proceedings in the courts. The Mandatory Provisions provide that such disputes should be submitted to arbitration at either the HKIAC or the CIETAC, at the claimant's choice.

Statutory reserve fund withdrawal

Under the PRC Company Law, when a joint stock limited company allocating the after-tax profits of the current year, a company shall allocate (10) ten percent of its profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong laws.

Remedies of the company

Under the PRC Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages. In addition, the Listing Rules require listed companies' articles of association to provide for remedies of the company similar to those available under Hong Kong laws (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

Dividends

A company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC laws on any dividends or other distributions payable to a shareholder. Under Hong Kong laws, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. A company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Fiduciary duties

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company's interests. Furthermore, the Companies Ordinance has codified the directors' statutory duty of care.

Under the PRC Company Law, directors, supervisors and senior management should be loyal and diligent. Under the Mandatory Provisions, directors, supervisors and senior management are not permitted, without the approval of the shareholders' general meeting, to engage in any activities which compete with or damage the interests of their company.

Closure of register of members

The Companies Ordinance requires that the register of members of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days under certain circumstances) in a year, whereas, as required by the PRC Company Law and the Mandatory Provisions, share transfers shall not be registered within 30 days before the date of a shareholders' general meeting or within five days before the base date set for the purpose of distribution of dividends.

Set out below is a summary of the principal provisions of the Articles of Association, the objective of which is to provide investors with an overview of the Articles of Association.

As the data contained below is in summary form, it may not contain all the information that may be important to potential investors. Copies of the full English and Chinese texts of the Articles of Association are available for inspection as mentioned in "Appendix VII — Documents Delivered to the Registrar of Companies and Documents on Display".

The Articles of Association, which is adopted by the shareholders in the general meeting held on February 11, 2022 (the "**2022 First Shareholder Meeting**") and subsequently revised by the Board of Directors on March 25, 2022 pursuant to the authorization by the 2022 First Shareholder Meeting, will become effective on the date that the overseas-[**REDACTED**] foreign shares of the Company are [**REDACTED**] on the Stock Exchange and replace the Articles of Association at the original registration in Administration for Market Regulation.

DIRECTORS AND OTHER SENIOR MANAGEMENT

Power to allot and issue Shares

There is no provision in the Articles of Association empowering the directors to allot and issue shares.

To increase the registered capital of the Company, the proposal must be submitted for approval by a special resolution at a general meeting.

Power to dispose of the assets of the Company or any subsidiary

The Board shall not dispose of or agree to dispose of any fixed assets without approval by the general meeting if the sum of the expected value of the fixed assets to be disposed of and the value derived from the disposal of fixed assets within four months before such proposal to dispose of the fixed assets exceeds 33% of the value of the fixed assets as shown on the latest audited balance sheet considered and approved by the general meeting. Disposals of the fixed assets mentioned herein include transfer of certain asset interests, but do not include guarantee provided by pledge of fixed assets.

The effectiveness of the disposal of the fixed assets shall not be affected by any breach of the above paragraph.

Remunerations and compensation for loss of office

The Company shall enter into a contract in writing with each of the directors or supervisors wherein his/her emoluments are stipulated, subject to prior approval at a general meeting. The aforesaid emoluments include:

(a) emoluments in respect of his service as a director, supervisor or an officer of the Company;

(b) emoluments in respect of his service as a director, supervisor or an officer of any subsidiary of the Company;

(c) emoluments in respect of the provision of other services in connection with the management of the affairs of the Company or any of its subsidiaries;

(d) payment by way of compensation for loss of office, or as consideration for or in connection with his retirement from office.

No proceedings may be brought by a director or supervisor against the Company for anything due to him in respect of matters mentioned above except pursuant to the aforesaid contract.

The Company shall disclose to shareholders the remuneration received by directors, supervisors and senior officers from the Company on a regular basis.

The contracts concerning the emoluments between the Company and its directors or supervisors should provide that in the event that the Company is acquired, the directors and supervisors shall, subject to the prior approval of the general meeting, have the right to receive compensation or other payment in respect of his loss of office or retirement. For the purpose of the paragraph, an acquisition of the Company means either:

(a) an offer made by any person to all the shareholders;

(b) an offer made by any person with a view to the offeror becoming a controlling shareholder. See the definition of "Controlling Shareholder" in "— Rights of minority shareholders".

If the relevant director or supervisor does not comply with above paragraph, any sum so received by him shall belong to those persons who have sold their shares as a result of such offer. The expenses incurred in distributing that sum pro rata amongst those persons shall be borne by the relevant director or supervisor and not paid out of that sum.

Loans to Directors, Supervisors and senior management

The Company shall not directly or indirectly make a loan to, or provide any security in connection with the making of a loan to a director, supervisor, general manager or other officer of the Company or of the Company's parent company or any of their respective associates.

The following circumstances are not subject to above prohibition:

(a) the provision by the Company of a loan or a guarantee of a loan to a company which is a subsidiary of the Company;

(b) the provision by the Company of a loan or a guarantee in connection with the making of a loan or any other funds available to any of its directors, supervisors, general manager and other officers to meet expenditure incurred or to be incurred by him for the purposes of the Company or for the purpose of enabling him to perform his duties properly, in accordance with a service contract approved by the shareholders in general meeting;

(c) the Company may make a loan to or provide a guarantee in connection with the making of a loan to any of the relevant directors, supervisors, general manager and other officers and their respective associates in the ordinary course of its business on normal commercial terms, provided that the ordinary course of business of the Company includes the lending of money or the giving of guarantees.

A loan made by the Company in breach of the above paragraph shall be forthwith repayable by the recipient of the loan regardless of the terms of the loan.

Any guarantee for a loan provided by the Company in breach of the above paragraph shall be unenforceable against the Company, unless:

(a) at the time the loan was made to an associate of any of the directors, supervisors, general manager and other officers of the Company or of the Company's parent company, the lender was not aware the relevant circumstances;

(b) the security provided by the Company has been lawfully disposed of by the lender to a bona fide purchaser.

The guarantee as referred to in the preceding paragraph includes the act of the guarantor to undertake the responsibility or provide property to ensure that the obligor fulfills the obligations.

Financial assistance to acquire Shares of the Company

The Company or its subsidiaries (including affiliates of the Company) shall not at any time to provide any financial assistance to purchasers or potential purchasers of the Company's shares in any way. The aforesaid purchasers include persons directly or indirectly undertaking obligations because of the purchase of the Company's shares.

The Company or its subsidiaries (including affiliates of the Company) shall not at any time or in any form provide any financial assistance to the aforesaid obligors for the purpose of reducing or discharging their obligations.

Financial assistance referred to in the Articles of Association includes (but is not limited to) the following:

(a) gift;

(b) guarantee (including the case where the guarantor undertakes liability or provides property to ensure fulfillment of obligations by the obligor), compensation (excluding compensation for the Company's own error), termination or waiver of rights;

(c) provision of loan or execution of contract under which the Company fulfils obligations prior to other parties, change of the said loan and the parties to the contract, and transfer of the said loan and rights under the contract;

(d) provision of any other form of financial assistance when the Company is insolvent, has no net assets or its net assets are likely to decrease significantly.

Obligations referred to in the above paragraph include the obligations undertaken by the obligor for entering into a contract or making an arrangement (regardless whether the said contract or arrangement is enforceable or whether it is undertaken by the obligor individually or jointly with others) or for changing his financial position in any form.

The following acts are not deemed as prohibited, unless prohibited by the relevant laws, administrative regulations, departmental rules and normative documents:

(a) the Company provides the relevant financial assistance truthfully in the interest of the Company and the said financial assistance is not mainly intended to buy back the Company's shares or the said financial assistance is part of a general plan of the Company;

(b) the Company distributes its properties as dividends in accordance with the law;

(c) the Company distributes shares as dividends;

(d) the Company decreases the registered capital, buys back shares and adjusts the equity structure in accordance with the Articles of Association;

(e) the Company, within its business scope, provides loan for its normal business operations (but such financial assistance shall not give rise to a decrease of the net assets of the Company, or despite a decrease, such financial assistance is deducted from the distributable profit of the Company);

(f) the Company provides loan for the employee stock ownership plan (but such financial assistance shall not give rise to a decrease of the net assets of the Company, or despite a decrease, such financial assistance is deducted from the distributable profit of the Company).

Disclosure of Interests in Contracts with the Company

Where a director, supervisor, general manager and other officer of the Company is in any way, directly or indirectly, materially interested in a contract, transaction or arrangement or proposed contract, transaction or arrangement with the Company, (other than his contract of service with the Company), he shall declare the nature and extent of his interests to the Board at the earliest opportunity, whether or not such contract, transaction or arrangement therefor is otherwise subject to the approval of the Board.

Unless the interested director, supervisor, general manager and other officer discloses his interests in accordance with the requirements of the preceding paragraph of this article and the contract, transaction or arrangement is approved by the Board at a meeting in which the interested director, supervisor, general manager and other officer is not counted in the quorum and retrains from voting, such contract, transaction or arrangement is voidable at the instance of the Company except as against a bona fide party thereto acting without notice of the breach of duty by the interested director, supervisor, general manager and other officer.

A director, supervisor, general manager and other officer of the Company is deemed to be interested in a contract, transaction or arrangement in which an associate of him is interested.

Where a director, supervisor, general manager and other officer of the Company gives to the Board a general notice in writing stating that, by reason of the facts specified in the notice, he is interested in contracts, transactions or arrangements of any description which may subsequently be made by the Company, such notice shall be deemed for the purposes of the above paragraph in the Articles of Association to be a sufficient declaration of his interests, so far as the content stated in such notice is concerned, provided that such general notice shall have been given before the date on which the question of entering into the relevant contract, transaction or arrangement is first taken into consideration on behalf of the Company.

REMUNERATION

The remuneration of Directors must be approved by shareholders at a general meeting. See "Remunerations and Compensation for Loss of Office" above.

APPOINTMENT, REMOVAL AND RETIREMENT

A person may not serve as a director, supervisor, general manager and other senior management of the Company if any of the following circumstances apply:

(a) a person without legal or with restricted legal capacity;

(b) a person who has been found guilty of sentenced for corruption, bribery, infringement of property, misappropriation of property or sabotaging the social economic order where less than a term of 5 years have elapsed since the sentence was served; or a person who has been deprived of his political rights, in each case where less than 5 years have elapsed since the sentence was served;

(c) a person who is a former director, factory manager or general manager of a company or enterprise which has been entered into insolvent liquidation because of mismanagement and he/she is personally liable for the insolvency of such company or enterprise, where less than 3 years have elapsed since the date of the completion of the insolvency and liquidation of the company or enterprise;

(d) a person who is a former legal representative of a company or enterprise which had its business licence revoked due to a violation of the law and who incurred personal liability, where less than 3 years has elapsed since the date of the revocation of the business licence;

(e) a person who has a relatively large amount of debts due and outstanding;

(f) a person who is under criminal investigation by judicial organization for the violation of the criminal law which is not yet concluded;

(g) a person who is not eligible to act as a leader of an enterprise according to laws and administrative regulations;

(h) a non-natural person;

(i) currently being barred by the China Securities Regulatory Commission from participating in the securities market;

(j) a person convicted of the contravention of provisions of relevant securities regulations by a relevant government authority, and such conviction involves a finding that he has acted fraudulently or dishonestly, where less than 5 years has elapsed since the date of the conviction; or

(k) other circumstances as required under laws, administrative regulations, departmental rules, regulatory documents, regulations of relevant regulatory authorities.

Where the Company elects, appoints or employs a director, a supervisor, the general manager and other senior management to which any of the above circumstances applies, such election, appointment or employment shall be null and void. A director, a supervisor, the general manager and other senior management to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the Company.

The validity of an act of a director, general manager and other senior management on behalf of the Company is not, as against a bona fide third party, affected by any irregularity in his office, election or any defect in his qualification.

CREDIT POWERS

The Articles of Association do not specifically provide for the manner in which borrowing powers may be exercised nor do they contain any specific provision in respect of the manner in which such borrowing powers may be amended, except for:

(a) provisions which authorize the Board to formulate proposals on the issue and [**REDACTED**] of bonds or other securities issued by the Company;

(b) provisions which provide that the issuing of any class of shares, warrants and other similar securities by the Company shall be passed by the general meeting by a special resolution.

AMENDMENTS TO THE ARTICLES OF ASSOCIATION OF THE COMPANY

Under any one of the following circumstances, the Company shall amend its Articles of Association:

(a) after amendment has been made to the Company Law or relevant laws or administrative regulations, the contents of the Articles of Association shall conflict with the amended laws or administrative regulations;

(b) the changes that the Company have undergone are inconsistent with the records made in the Articles of Association;

(c) the general meeting decides that the Article of Association should be amended.

The shareholders may authorize the Board of the Company by ordinary resolution at the general meeting:

(a) in case of increase of registered share capital of the Company, the Board of the Company is entitled to amend the relevant content regarding the registered capital of the Company in the Articles of Association in accordance with the actual circumstances;

(b) in case of alteration of the text or order of the provisions required by the relevant regulatory authority during the registration, audit and approval of the Articles of Association of the Company approved by the general meeting, the Board of the Company is entitled to make the corresponding amendments according to the requirements of the relevant regulatory authority.

Amendments to the Articles of Association passed by resolutions at the general meeting shall be required to be examined and approved by the competent authorities, and shall be submitted to the competent authorities for approval; where the amendments involve the registered particulars of the Company, procedures for change of registration shall be handled in accordance with the law.

CHANGE OF RIGHTS OF EXISTING SHARES OR CLASSES OF SHARES

Rights conferred on any class of shareholders in the capacity of shareholders may not be varied or abrogated unless approved by a special resolution of a general meeting and by holders of shares of that class at a separate meeting conducted in accordance with stipulated in the Articles of Association. If the rights of any class of shareholders are changed or abolished due to changes in laws, administrative regulations, listing rules of the place where the company's shares are [**REDACTED**], and decisions made by regulatory agencies in accordance with the law, the approval of the general meeting of shareholders or the class meeting is not required. If the shareholders of domestic shares of the company transfer all or part of the shares they hold to overseas investors and [**REDACTED**] and trade overseas, or convert all or part of domestic shares (or other [**REDACTED**] shares) into foreign shares [**REDACTED**] overseas and [**REDACTED**] them on overseas stock exchanges, the act of [**REDACTED**] and trading should not be regarded as the company's intention to change or abolish the rights of class shareholders, which does not require the approval of the general meeting of shareholders or the class meeting.

The following circumstances shall be deemed to be variation or abrogation of the class rights of a class:

(a) to increase or decrease the number of shares of such class, or increase or decrease the number of shares of class having voting or equity rights or privileges equal or superior to those of the shares of such class;

(b) to effect an exchange of all or part of the shares of such class into shares of another class or to effect an exchange or create a right of exchange of all or part of the shares of another class into the shares of such class;

(c) to remove or reduce rights to accrued dividends or rights to cumulative dividends attached to shares of such class;

(d) to reduce or remove a dividend preference or a liquidation preference attached to shares of such class;

(e) to add, remove or reduce conversion privileges, options, voting rights, transfer, pre-emptive rights, or rights to acquire securities of the Company attached to shares of such class;

(f) to remove or reduce rights to receive payment payable by the Company in particular currencies attached to shares of such class;

(g) to create a new class having voting or equity right or privileges equal or superior to those of the shares of such class;

(h) to restrict the transfer or ownership of the shares of such class or add to such restriction;

(i) to issue rights to subscribe for, or convert into, shares in the Company of such class or another class;

(j) to increase the rights or privileges of shares of another class;

(k) to restructure the Company where the proposed restructuring will result in different classes of shareholders bearing a disproportionate burden of such proposed restructuring;

(l) to vary or abrogate provisions in this section.

Shareholders of the affected class, whether or not otherwise having the right to vote at general meetings, shall nevertheless have the right to vote at class meetings in respect of matter concerning (b) to (h), (k) to (l) of the above Article, but interested shareholder shall not be entitled to vote at class meetings.

The meaning of the foregoing "interested shareholder" is:

(a) in the case of a repurchase of shares by offers to all shareholders pro rata according to the Articles of Association or public dealing on a stock exchange, a "controlling shareholder" within the meaning of the Articles of Association;

(b) in the case of a repurchase of shares by an off-market contract according to the Articles of Association, a holder of the shares to which the proposed contract relates;

(c) in the case of a restructuring of the Company, a shareholder within a class who bears less than a proportionate burden imposed on that class under the proposed restructuring or who has an interest in the proposed restructuring different from the interest of shareholders of that class.

Resolutions of a class meeting shall be passed by votes representing more than two-thirds of the voting rights of shareholders of that class represented at the relevant meeting who are entitled to vote at class meetings.

When the Company is to hold a class meeting, a written notice shall be issued in accordance with the relevant provisions of the notice of shareholders' general meeting and shall inform all the registered shareholders of that class of the matters to be considered at the meeting as well as the date and venue of the meeting.

Notice of class meetings need only be served on shareholders entitled to vote thereat.

Except as otherwise provided under the Articles of Association, any class meetings shall be conducted in a manner as similar as possible to that of general meetings. The provisions of the Articles of Association relating to the manner of conducting any general meeting shall apply to any class meeting.

Other than the shareholders of other classes of shares, shareholders of domestic shares and overseas-listed foreign shares shall be deemed as shareholders of different classes.

The special procedures for voting at a class of shareholders shall not apply in the following circumstances:

(a) where the Company issues domestic shares and overseas-[**REDACTED**] foreign invested shares, upon the approval by a special resolution of its general meeting, either separately or concurrently once every 12 months, not exceeding 20% of each of its existing issued;

(b) where the Company's plan to issue domestic shares and overseas-[**REDACTED**] foreign invested shares at the time of its establishment is carried out within 15 months from the date of approval of the securities regulatory authority under the State Council;

(c) Shares (including domestic and foreign shares) already issued but not [**REDACTED**] of the Company, after approval from the securities regulatory authority under the State Council, are converted to overseas-[**REDACTED**] shares.

RESOLUTIONS-MAJORITY REQUIRED

Resolutions of the general meeting shall be divided into ordinary resolutions and special resolutions.

An ordinary resolution of a general meeting shall be passed by more than one half of the voting rights held by the shareholders (including proxies) present at the meeting.

A special resolution of a general meeting shall be passed by two-thirds of the voting rights held by the shareholders (including proxies) present at the meeting.

VOTING RIGHTS

A shareholder (including his/her proxy) shall exercise his/her voting rights based on the number of shares held. Each share shall have one vote. No voting rights shall attach to the shares held by the Company, and such shares shall not be counted among the total number of shares with voting rights present at a general meeting.

If the laws, administrative regulations, regulatory rules of the place where the shares of the Company are [**REDACTED**] stipulate that any shareholder shall waive his/her voting right on a certain resolution or limit any shareholder to cast affirmative or negative vote on certain matter, and in case of any violation of such relevant stipulation or limitations, votes casted by such shareholders or proxies thereof shall not be adopted.

Unless the resolutions on relevant procedures of a general meeting or administrative matters which can be decided by the chairman in the spirit of honesty and credibility and shall be voted on by show of hands, voting for a general meeting shall be made by ballot.

At the time of voting, any shareholder who has two or more votes (including the proxies of such shareholders) needs not to use all votes for or against any resolution or to abstain from voting on such resolution.

REQUIREMENT FOR GENERAL MEETINGS

General meetings shall be divided into annual general meetings and extraordinary general meetings. Annual general meetings are held once every year and within 6 months from the end of the preceding accounting year.

The Board shall convene an extraordinary general meeting within two months after the occurrence of any one of the following circumstances:

(a) where the number of directors falls short of the minimum number required by the Company Law or is no more than two-thirds of the number required by the Articles of Association;

(b) where the unrecovered losses of the Company amount to one-third of its total paid up share capital;

(c) where shareholder(s), individually or jointly, holding 10% or more of the Company's issued and outstanding shares carrying voting rights request(s) in writing the convening of an extraordinary general meeting (the number of shares held shall be calculated as at the date when the shareholder(s) provide(s) the written request);

(d) where the Board considers it necessary;

(e) where the board of supervisors proposes to call for such a meeting;

(f) other circumstances stipulated by laws, administrative regulations, departmental rules, the listing rules of the place where the shares of the Company are [**REDACTED**] or the Articles of Association.

The venue of a general meetings of the Company shall be the place where the Company is located or the place specified in the notice of the general meeting.

ACCOUNTS AND AUDIT

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations and the requirement of relevant regulatory departments of the PRC. Any other requirements as required by the securities regulatory authority at the place where the shares of the Company are [**REDACTED**] shall prevail.

The Company's fiscal year adopts the Gregorian calendar year system, that is, the fiscal year starts from January 1 to December 31 of the Gregorian calendar every year.

The financial statements of the Company shall, in addition to being prepared in accordance with the PRC accounting standards and regulations, be prepared in accordance with either international amounting standards, or that of the overseas [**REDACTED**] place. If there is any material difference between the financial statements prepared respectively in accordance with the two accounting standards, such difference shall be stated in an appendix to the financial statements. When the Company is to distribute its after-tax profits, the lower of the after-tax profits as shown in the two financial statements shall be adopted.

The Company shall publish its financial reports twice every fiscal year, that is, the interim financial report shall be published within 60 days after the first 6-month period of each fiscal year and the annual financial report shall be published within 120 days after the expiration of each fiscal year.

Any interim results or financial information published or disclosed by the Company must be prepared and presented in accordance with the PRC accounting standards and regulations, and also in accordance with either international accounting standards or that of the overseas [**REDACTED**] place.

The Company's financial reports shall be made available for shareholders' inspection at the Company at least 21 days before the date of every annual general meeting. Each shareholder of the Company shall be entitled to obtain a copy of the financial reports referred to in this section.

The Company shall, at least 21 days before the annual general meeting, send the aforesaid report by prepaid mail to each shareholder of overseas [**REDACTED**] foreign shares, and the address of the recipient shall be the address registered in the roster of shareholders.

NOTICE OF MEETING AND MATTERS TO BE CONSIDERED

The general meeting is the organ of authority of the Company, which exercises its functions and powers in accordance with laws:

(a) to decide on operational policies and investment plans of the Company;

(b) to elect and replace the directors and supervisors who are shareholder representatives, and to decide on matters relevant to remuneration of directors and supervisors;

(c) to consider and approve reports of the Board;

(d) to consider and approve reports of the board of supervisors;

(e) to consider and approve annual financial budget plans and final accounting plans of the Company;

(f) to consider and approve the profit distribution plan and loss recovery plan of the Company;

(g) to determine the increases or decrease of the registered capital of the Company;

(h) to determine the issuance of corporate bonds or other securities by the Company and [**REDACTED**] plan;

(i) to determine matters such as the merger, division, dissolution, liquidation or change;

(j) to amend the Articles of Association;

(k) to determine the appointment of, removal of and non-reappointment of an auditor by the Company;

(l) to consider and approve the provision of guarantees to third parties that shall be approved at a general meeting required by the Articles of Association;

(m) to consider matters relating to the purchases and disposals of material assets, which are more than 30% of the latest audited total assets of the Company, within one year;

(n) to consider and approve the related transactions that shall be considered and approved at a general meeting required by laws, administrative regulations, the listing rules of the place where the shares of the Company are [**REDACTED**] and the Articles of Association;

(o) to consider the formulation, amendment and implementation of share incentive plans;

(p) to consider and approve the proposal raised by shareholders who, individually or in the aggregate, hold 3% or more of the total number of voting shares of the Company;

(q) to review other matters which, in accordance with laws, administrative regulations, departmental rules, the listing rules of the places where the shares of the Company are [**REDACTED**], or the provisions of the Articles of Association, shall be approved at a general meeting.

The general meeting can authorize or entrust the Board to handle the matters authorized or entrusted thereby, provided that the laws and regulations, and the mandatory laws and regulations of place where the shares of the Company are [**REDACTED**] are not violated.

The following matters shall be approved by ordinary resolution at a general meeting:

(a) work reports of the Board and the board of supervisors;

(b) profit distribution plan and loss recovery plan formulated by the Board;

(c) appointment and removal of members of the Board and the board of supervisors, their remuneration and method of payment;

(d) annual financial budgets and statements of final accounts, balance sheet, income statement and other financial statements of the Company;

(e) annual report of the Company;

(f) hiring, dismissing or not reappointing accounting firms;

(g) any matters not otherwise required by the laws, administrative regulations, regulatory rules of the place where the shares of the Company are [**REDACTED**] or the Articles of Association (unless matters required by the Articles of Association to be passed by special resolution).

The following matters shall be approved by special resolution at a general meeting:

(a) to increase or reduce the registered capital of the Company and issue any type of shares, options and other similar types of securities;

(b) the plan of issuance and [**REDACTED**] of corporate bonds;

(c) to resolve on the division, merger, dissolution, liquidation or transformation of the Company;

(d) to make amendments to these Articles of Association;

(e) to consider purchase or sale of material assets by the Company within one year, or a guarantee amount exceeding 30% of the total assets in the most recent audit period of the Company;

(f) to formulate, revise and implement a share incentive scheme;

(g) other matters as stipulated by the laws, administrative regulations, regulatory rules of the place where the shares of the Company are [**REDACTED**] or these Articles of Association, and matters deemed by the general meeting by ordinary resolution to have material effect on the Company and necessary for passing by special resolution.

Where the Company convenes an annual general meeting, a written notice shall be issued at least 21 days (excluding both the date of notice and the date of meeting) prior to the annual general meeting and at least 15 days (excluding both the date of notice and the date of meeting) prior to the extraordinary general meeting (unless the Company can demonstrate that reasonable written notice can be issued within a shorter period of time). If there are other provisions in the laws, regulations and by the securities regulatory authorities of the place where the shares of the Company are [**REDACTED**], such provisions shall prevail.

The notice of the general meeting shall be given in writing and contain the following:

(a) the date, venue and duration of the meeting;

(b) matters and proposals submitted for consideration at the meeting;

(c) an obvious statement that all shareholders are entitled to attend the general meeting in person, or appoint in writing proxies to attend and vote on his or her behalf and that such proxies need not be shareholders of the Company;

(d) name and telephone number of the permanent contact person;

(e) such information and explanation as necessary for shareholders to make informed decisions in connection with the matters to be discussed; this principle shall apply (but not be limited to) when proposals are made to merge the Company, to repurchase shares of the Company, to reorganize its share capital or to effect any other reorganization of the Company and specific conditions and contracts (if any) of the proposed transaction together with proper explanations of the causes and consequences of any such proposals;

(f) the nature and extent of the material interests of any director, supervisor or senior management members in the transaction to be discussed and the difference in case of the effect of the transaction to be discussed on such director, supervisor or senior management member as shareholders insofar as it differs from the effect on the shareholders of the same class;

(g) the full text of any special resolution proposed to be passed at the meeting;

(h) the date and place for serving the power of attorney authorizing the proxy to vote;

(i) the record date for the determination of the entitlements of shareholders to the general meeting.

The notice and supplementary notice of a general meeting shall adequately and completely disclose the specific contents of all proposals. Where the opinions of the independent directors are required on the issues to be discussed, such opinions and reasons thereof shall be disclosed when the notice or supplementary notice of the general meeting is served.

Unless otherwise stipulated by the laws, regulations and these Articles of Association, the notice of a general meeting shall be delivered by hand or prepaid mail to all shareholders (whether they are entitled to vote at the general meeting or not). The address of the recipient shall be the address registered in the register of members. For holders of domestic shares, the notice of a general meeting may also be in the form of an announcement.

The announcement mentioned above shall be published in one or more newspapers designated by the securities regulatory authorities under the State Council. All holders of domestic shares shall be deemed as having receive the notice of the general meeting once the announcement is published.

The notice of the general meeting sent to holders of H Shares may be published on the designated website of the Stock Exchange and the website of the Company. All holders of overseas [**REDACTED**] shares shall be deemed as having receive the notice of the general meeting once the announcement is published.

TRANSFER OF SHARES

Unless otherwise specified in the laws and administrative and by the securities regulatory authorities in the place where the shares of the Company, the paid up shares of the Company can be freely transferred in accordance with laws and are not subject to any lien. Shares of the Company could be granted, inherited and pledged in accordance with relevant laws, administrative regulations and requirement of the Articles of Association.

All transfers of H shares shall be effected by transfer document in writing in a general or common form or in any other form acceptable to the Board, including the standard transfer form or form of transfer specified by the Stock Exchange from time to time. The transfer document in writing may be signed by hand or (where the transferor or transferee is a corporation) stamped with the company's seal. If the transferor or transferee is a recognized clearing house as defined by the relevant provisions that come into effect from time to time according to the laws of Hong Kong (hereinafter referred to as the "**Recognized Clearing House**") or its nominee, the transfer document in writing may be signed by hand or in printed form.

All transfer documents shall be maintained in the legal address of the Company or such places as the Board may designate from time to time.

The Company shall not accept its own shares as pledge subject.

Shares of the Company held by the promoters shall not be transferred within one year after incorporation of the Company. Shares already issued by the Company before [**REDACTED**] shall not be transferred within one year after the shares of the Company are [**REDACTED**] on the Stock Exchange.

The directors, supervisors and senior executives shall report to the Company about their shareholdings and changes thereof and shall not transfer more than 25% of their shares per annum during their terms of office; the shares they hold in the Company shall not be transferred within one year after the shares of the Company are [**REDACTED**]. The aforesaid persons shall not transfer their shares in the Company within half a year after they terminate service with the Company.

Where the relevant regulations of the securities regulatory authorities of the place where the shares of the Company are [**REDACTED**] provide otherwise in respect of any transfer of any overseas [**REDACTED**] foreign shares, such regulations shall apply.

POWER FOR THE COMPANY TO REPURCHASE ITS OWN SHARES

The Company may, in the following circumstances, buy back its outstanding shares in accordance with the law, administrative regulations, department rules, listing rules of the place where the shares of the Company are [**REDACTED**] and requirement of this Articles of Associations:

(a) When cancelling shares to decrease registered capital of the Company;

(b) When merging with other companies holding shares of the Company;

(c) When shares are being used in the employee stock ownership plan or as equity incentive;

(d) When shareholders objecting to resolutions of the general meeting concerning merger or division of the Company require the Company to buy their shares;

(e) When shares are being used to satisfy the conversion of corporate bonds convertible into shares issued by the Company;

(f) When safeguarding corporate value and shareholders' equity as the Company deems necessary;

(g) Other matters as stipulated by the laws, administrative regulations, listing rules of the place where the shares of the Company are [**REDACTED**];

Except for the abovementioned circumstances, the Company will not conduct any activities buying or selling its shares.

Where the Company repurchases its shares in the circumstances set out in items (a) and (b) above, it shall be subject to approval at the general meeting; where the Company repurchases its shares in the circumstances set out in items (c), (e) and (f) above, it may be resolved by more than two-thirds of directors present at a meeting of the Board in accordance with the authorization of the general meeting.

In the event that the Company repurchases its shares in accordance with the above provisions, such Shares shall be cancelled within 10 days upon such repurchase in the circumstance set out in item (a); shall be transferred or cancelled within 6 months in the circumstances set out in items (b) and (d); the aggregate number of shares held by the Company shall not exceed 10% of the total issued shares of the Company, and shall be transferred or cancelled within 3 years in the circumstances set out in items (c), (e) and (f).

Where the Company repurchases its shares, it shall perform its information disclosure obligations in accordance with laws.

The Company may buy back its shares in any of the following ways:

(a) Issuing a buyback offer to all shareholders according to an equal percentage;

(b) Buying back through open transaction in the Stock Exchange;

(c) Buying back through agreement outside the Stock Exchange;

(d) Other methods as permitted by laws and administrative regulations and recognized by regulatory authorities.

In buying back shares through agreement outside the Stock Exchange, the Company shall seek prior approval at a general meeting in accordance with the Articles of Association. With prior approval at the general meeting in the same way, the Company may cancel or change the contract already concluded in the aforesaid manner or waive any right under the contract.

The share buyback contract mentioned in the preceding paragraph includes (but is not limited to) agreement to undertake share buyback obligations and obtain share buyback rights.

The Company shall not transfer the share buyback contract or any right thereunder.

Unless the Company is under liquidation, the Company shall observe the following regulations when buying back its outstanding shares:

(a) If the Company buys back shares at par value, the payment shall be deducted from the book balance of distributable profit of the Company and the proceeds from issuance of new shares for buying back old shares;

(b) If the Company buys back shares above par value, the part equivalent to the par value shall be deducted from the book balance of distributable profit of the Company and the proceeds from issuance of new shares for buying back old shares; the part above the par value shall be processed as follows:

  i. Deducted from the book balance of distributable profit of the Company if the shares bought back were issued at par value;

  ii. Deducted from the book balance of distributable profit of the Company and the proceeds from issuance of new shares for buying back old shares if the shares bought back were issued above par value; but the amount deducted from the proceeds from issuance of new shares shall not exceed the total premium obtained at the time of issuance of the shares bought back and shall not exceed the amount (including premium from issuance of new shares) in the premium account (or capital reserve account) of the Company at the time of buyback;

(c) The monies paid by the Company for the following purposes shall be deducted from the distributable profits of the Company:

  i. Acquiring the right to buy back its shares;

  ii. Changing the share buyback contract;

  iii. Cancelling its obligations under the share buyback contract.

(d) After the par value of the cancelled shares is deducted from the registered capital of the Company pursuant to relevant regulations, the amount deducted from the distributable profit for paying the par value of the shares bought back shall be stated in the premium account (or capital reserve account) of the Company.

RIGHT OF THE COMPANY'S SUBSIDIARIES TO OWN SHARES IN THE COMPANY

There are no provisions in the Articles of Association restricting a subsidiary of the Company from owning any of the shares of the Company.

DIVIDENDS AND OTHER METHODS OF PROFIT DISTRIBUTION

The Company may distribute profit in the form of cash or shares.

The Company pays cash dividends and other payments to domestic shareholders in RMB. The Company pays cash dividends and other payments to foreign shareholders, which are denominated and declared in RMB, and paid in foreign currencies. The foreign currency required by the Company to pay cash dividends and other payments to foreign shareholders shall be handled in accordance with the relevant state regulations on foreign exchange management.

Unless otherwise stipulated by relevant laws and regulations, when paying cash dividends and other payments in foreign currency, the exchange rate shall be the average of the central parity rates announced by the People's Bank of China one calendar week prior to the day when the dividends and other payments are announced.

The Company shall appoint a payment receiving agent for holders of overseas [**REDACTED**] foreign shares in Hong Kong. The payment receiving agent shall receive on behalf of such shareholders any dividends or other amounts payable by the Company to them in respect of the overseas [**REDACTED**] foreign shares. The payment receiving agent appointed by the Company shall satisfy the requirements under the laws of the place where the Company's shares are [**REDACTED**] or the rules of the relevant stock exchange.

SHAREHOLDERS' PROXY

Any shareholder who is entitled to attend the general meeting and vote thereat may attend the general meeting in person or appoint one or more proxies (who may not be a shareholder) to attend and vote on its behalf. A shareholder shall authorize his or her proxy in writing and the power of attorney shall be signed by the proxy or the agent authorized in writing by the proxy. Where the proxy is a corporate, the chop of the corporate should be affixed, or the director or the agent officially entrusted shall sign such power of attorney.

A proxy is entitled to exercise the following rights pursuant to the appointment made by the appointing shareholder:

(a) the same right as the shareholder to speak at the general meeting;

(b) authority to demand or join in demanding a poll;

(c) the right to vote by show of hands or on a poll; however, a proxy of a shareholder who has appointed more than one proxy may only vote on a poll.

The instrument appointing a proxy shall be deposited at the Company's domicile or such other place as specified in the notice of the meeting at least 24 hours before the time appointed for holding the meeting at which the instrument proposes to vote, or 24 hours before the time appointed for taking of poll. Where such instrument is signed by a person under a power of attorney or other authority on behalf of the appointer, that power of attorney or other authority is required to be notarized. A notarized copy of that power of attorney or other authority together with the instrument appointing a proxy is required to be deposited at the Company's domicile or such other place as specified in the notice of the meeting.

If the appointer is a corporation shareholder, the legal representative (person in charge) or such person who is authorized by the resolution of its board or other governing body to act as its representative may attend the general meeting of the Company.

A vote given by a proxy in accordance with the terms of an instrument of proxy shall be valid notwithstanding the previous death or loss of capacity of the appointer or revocation of the proxy or power of authority under which the proxy was executed, or the transfer of the share in respect of which the proxy is given, provided that no notice in writing of such death, insanity, revocation or transfer as aforesaid has been received by the Company before the commencement of the meeting at which the proxy is used.

RIGHTS OF SHAREHOLDERS (INCLUDING INSPECTION OF REGISTER OF MEMBERS)

Ordinary shareholders of the Company shall enjoy the following rights:

(a) the rights to receive dividends and other forms of distribution in proportion to the number of shares held by them;

(b) the rights to request, convene, chair, attend or appoint proxy to attend general meetings and exercise corresponding voting rights in accordance with laws;

(c) the rights to supervise and manage the operation of the Company and to put forward proposals and raise inquiries;

(d) the rights to transfer, donate, or pledge shares held by them in accordance with laws, administrative regulations and the Articles of Association;

(e) the rights to obtain relevant information in accordance with the Articles of Association of the Company, including:

    i. to obtain a copy of the Articles of Association, subject to payment of the cost of such copy;

    ii. to inspect and copy, subject to payment of a reasonable charge:

        (i) all parts of the register of members (the list of all shareholders at the close of trading on the record date of the Company's latest periodic report);

(ii) personal particulars of each of the directors, supervisors, general manager and other senior management of the Company, including: a. current and previous names and aliases; b. main address (domicile); c. nationality; d. full-time and all other part-time occupations and duties; e. identification documents and their number;

(iii) the status of the Company's share capital;

(iv) reports (breakdown by domestic shares and foreign shares (and, if applicable, H Shares)) of the aggregate par value, number of shares, highest and lowest prices paid by the Company in respect of each class of shares bought back by the Company since the end of the last financial year and all the expenses paid by the Company therefor;

(v) minutes of general meetings (only available for shareholders' inspection) and copies of the Company's resolutions of general meetings, Board meetings and meeting of Board of Supervisors;

(vi) the latest audited financial statements of the Company, and the reports of directors, auditors, and supervisors;

(vii) copy of the latest annual return filed with the Administration for Market Regulation or other competent authorities;

(viii) special resolutions of the Company.

iii. counterfoils of corporate bonds.

Documents of item ii (i), (iii), (iv), (v), (vi), (vii) and (viii) mentioned above shall be made available by the Company, according to the requirements of the Listing Rules, at the Company's address in Hong Kong, for the public and the H Shareholders to inspect free of charge (provided that minutes of general meetings are available for inspection by the shareholders only). When a shareholder requests to inspect the relevant information mentioned above or obtain such materials, he/she shall provide the Company with such written documents evidencing the class and amount of shares he/she holds in the Company. The Company may provide such information per the shareholder's request after verifying his/her identity.

(f) the rights to participate in the distribution of remaining assets of the Company corresponding to the number of shares held in the event of the termination or liquidation of the Company;

(g) the rights to demand the Company to acquire the shares held by them with respect to shareholders voting against any resolution adopted at the general meeting on the merger or division of the Company;

(h) other rights under the laws, administrative regulations, the regulatory rules of the place where the shares of the Company are [**REDACTED**] and these Articles of Association.

RIGHTS OF MINORITY SHAREHOLDERS

In addition to obligations imposed by the laws, administrative regulations or required by the regulatory rules of the place where the shares of the Company are [**REDACTED**], a controlling shareholder shall not exercise his voting rights in respect of the following matters in a manner prejudicial to the interests the shareholders generally or partially:

(a) to relieve a Director or Supervisor of his/her duty to act honestly in the best interests of the Company;

(b) to approve the expropriation by a Director or Supervisor (for his/her own benefit or for the benefit of another person), in any guise, of the Company's property, including (without limitation) opportunities beneficial to the Company; or

(c) to approve the expropriation by a Director or Supervisor (for his/her own benefit or for the benefit of another person) of the individual rights or interests of other shareholders, including (without limitation) rights to distributions and voting rights save for the Company's restructuring submitted to shareholders for approval and adopted by the general meeting in accordance with the Articles of Association.

The term "controlling shareholder" referred to in the Articles of Association means a person who satisfies any one of the following conditions:

(a) a person who, acting alone or in concert with others, has the power to elect a majority of the directors;

(b) a person who, acting alone or in concert with others, has the power to exercise or to control the exercise of 30% (inclusive) or more of the voting rights in the Company;

(c) a person who, acting alone or in concert with others, holds 30% (inclusive) or more of the issued and outstanding shares of the Company;

(d) a person who, acting alone or in concert with others, has de facto control over the Company in any other way.

PROCEDURES FOR LIQUIDATION

The Company shall be dissolved and liquidated upon the occurrence of the following events:

(a) the term of its operations set out in the Articles of Association has expired;

(b) a resolution for dissolution is passed by shareholders at a general meeting;

(c) dissolution is necessary due to a merger or division of the Company;

(d) the Company is legally declared insolvent due to its failure to repay debts as they become due;

(e) the Company's business license is revoked or the Company is ordered to close down or de-registered according to laws;

(f) where the Company gets into serious trouble in operation and management and its continuation may cause substantial loss to the interests of shareholders, and no solution can be found through any other channel, shareholders representing more than 10% of the voting rights of all shareholders of the Company may request the People's Court to dissolve the Company.

The Company may continue to exist by amending the Articles of Association in the event of the circumstance as set forth in item (a) of the preceding article.

The amendment to the Articles of Association according to the preceding article shall be passed by 2/3 of the voting rights held by shareholders present at the general meeting.

In the case of dissolution of the Company under items (a), (b), (e) and (f) of the preceding article, a liquidation committee shall be formed to commence liquidation within 15 days from the date of occurrence of events giving rise to dissolution. The members of the liquidation committee shall be determined by the directors or the general meeting. Where a liquidation committee is not established according to schedule, the creditors may apply to the People's Court to designate the relevant personnel to establish a liquidation committee to proceed with the liquidation.

In the case of dissolution of the Company under item (d) of the preceding article, the People's Court shall, according to relevant legal provisions, organize the shareholders, relevant departments and professionals to form a liquidation committee to carry out liquidation.

If the Board decides the Company shall carry out liquidation (except for liquidation resulting from the Company's declaration of bankruptcy), it shall state in the notice of the general meeting convened for this purpose that the Board has conducted comprehensive investigation on the Company's conditions and believes that the Company is able to pay off all its debts within 12 months following the commencement of liquidation.

The functions and powers of the Board of the Company shall terminate immediately when the general meeting adopts the resolution on liquidation.

The liquidation committee shall follow the directions of the general meeting to report on its income and expenditures, the Company's business and progress of liquidation at least once a year to the general meeting and make a final report to the general meeting at the end of liquidation.

The liquidation committee shall exercise the following functions and powers during the period of liquidation:

(a) to categorize the Company's assets and prepare a balance sheet and an inventory of assets respectively;

(b) to inform creditors by a notice or public announcement;

(c) to dispose of and liquidate any unfinished businesses of the Company;

(d) to pay all outstanding taxes and the taxes incurred from the process of liquidation;

(e) to settle claims and debts;

(f) to deal with the residual assets remaining after repayment by the Company of its debts;

(g) to represent the Company in any civil proceedings.

The liquidation committee shall, within 10 days of its formation, notify the creditors, and shall, within 60 days, make a public announcement in newspapers at least three times. Creditors shall, within 30 days of the receipt of the notice or within 45 days of the release of the public announcement in the case of failure to receive said notice, file their creditors' rights with the liquidation committee.

Where creditors file their creditors' rights, they shall explain about the matters related to creditors' rights, and shall provide the evidentiary materials. The liquidation committee shall register the creditors' rights. The liquidation committee may not clear off any of the debts of any creditors during the period of filing creditors' rights.

After the liquidation committee has sorted the Company's assets and prepared a balance sheet and an inventory of assets, it shall prepare a liquidation plan and submit it to the general meeting or the People's Court for confirmation.

The remaining assets should be paid off in the following order:

(a) to pay off the liquidation expenses;

(b) to pay off wages of employees, social insurance premiums and statutory compensation;

(c) to pay off the outstanding taxes;

(d) to pay off the debts of the Company;

(e) to be distributed in proportion to shareholding of the shareholders;

During the period of liquidation, the Company continues to exist but may not carry out any business operation that is not related to liquidation. Before the settlement of repayments as provided in the (a) to (d) of the above articles has been made, the Company's assets shall not be distributed to shareholders.

If the liquidation committee, having sorted the Company's assets and prepared the balance sheet and an inventory of assets, discovers that there are insufficient assets in the Company to pay off its debts, it shall apply to the People's Court immediately for a declaration of bankruptcy of the Company.

Upon the declaration of bankruptcy of the Company by the People's Court, the liquidation committee shall hand over the liquidation matters to the People's Court.

Following the completion of the liquidation, the liquidation committee shall prepare a liquidation report, a statement of income and expenses received and made during the liquidation period and a financial report, which shall be verified by a Chinese registered accountant and submitted the same to the general meeting or the People's Court for confirmation. The liquidation committee shall, within 30 days from the date of said confirmation made by the general meeting or relevant competent authorities, submit the documents referred to in the preceding paragraph to the companies registration authority and apply for cancellation of registration of the Company, and publish a public announcement relating to the termination of the Company.

OTHER IMPORTANT PROVISIONS FOR OUR COMPANY OR THE SHAREHOLDERS

General Provisions

The Company is a joint stock limited company with perpetual existence.

Pursuant to the Articles of Association, the shareholders may pursue actions against other shareholders, the shareholders may pursue actions against the directors, supervisors, general manager and other senior management members of the Company, the shareholders may pursue actions against the Company and the Company may pursue actions against its shareholders, directors, supervisors, general manager and other senior management. The actions, as referred to in the preceding paragraph, include the instituting of legal proceedings with a court or filing with an arbitral authority for arbitration.

After adoption by special resolution on the general meeting of the Company, the Articles of Association shall take effect and put into force from the date on which the H Shares issued by the Company are [**REDACTED**] on the Main Board of the Stock Exchange. Since the effective date of the Articles of Association, the original Articles of Association of the Company shall be automatically invalidated.

Increase of capital

The Company may increase capital based on the needs of operation and development and in accordance with the requirements of laws and regulations and resolution on the general meeting, by way of the following:

(a) [**REDACTED**] of shares;

(b) Non-[**REDACTED**] of shares;

(c) Placement and offer of new shares to existing shareholders;

(d) Conversion of reserve into share capital;

(e) Other means stipulated by laws and administrative regulations.

The Company's increase of capital by issuing new shares shall, after being approved in accordance with the provisions of the Articles of Association, be conducted in accordance with the procedures stipulated by relevant laws, administrative regulations of the State and the listing rules of the place where the shares of the Company are [**REDACTED**].

Deduction of capital

The Company may decrease its registered capital. The Company shall decrease its registered capital pursuant to the Company Law, other relevant regulations and the Articles of Association.

A balance sheet and an inventory of assets must be prepared by the Company if it needs to reduce registered capital.

The Company shall notify its creditors within 10 days from the date of the resolution for reduction of registered capital and shall publish a public announcement in newspapers within 30 days thereafter. The creditors are entitled to require the Company to settle the loans or to provide corresponding guarantees within 30 days after the receipt of the written notification, or in the event that no such notification is received, within 45 days after the date of the announcement.

Rights and obligations of shareholders

Shareholders shall enjoy rights and have obligations in accordance with the class and amount of shares held by them. Shareholders holding the same class of shares shall be entitled to equal rights and have equal obligations.

Ordinary shareholders of the Company shall enjoy the following rights, please refer to the paragraph headed "Rights of Shareholders (Including Inspection of Register of members)" above.

Ordinary shareholders of the Company shall have the following obligations:

(a) to abide by laws, administrative regulations and the Articles of Association;

(b) to pay for the shares based on the shares subscribed for and the manners in which they became shareholder;

(c) not to withdraw their paid share capital except in circumstances allowed by laws and regulations;

(d) not to abuse shareholder's rights and harm the legal interest of the Company or other shareholders; not to abuse the independent legal person status of the Company and the limited liability of the shareholders to impair the legal interests of creditors of the Company;

Where the shareholder's abuse of its power causes damage to other shareholders, he shall be liable to compensation in accordance with the law;

Where the shareholder has abused the Company's independent legal person status and shareholder's limited liability for debt evasion and caused serious damage to the creditor's interests, it shall bear joint liability for the debts of the Company;

(e) other obligations imposed by laws, administrative regulations, the regulatory rules of the place where the shares of the Company are [**REDACTED**] and the Articles of Association.

Shareholders are not liable for making any further contribution to the share capital other than as agreed by the subscribers of the shares on subscription.

General meeting

The general meeting is the organ of authority of the Company, which exercises its functions and powers in accordance with laws, please refer to the paragraph headed "Notice of meeting and matters to be considered" above.

Proposals of general meetings

Where the Company convenes a general meeting, the Board, the board of supervisors and shareholders individually or jointly holding more than 3% of the shares of the Company shall have the right to put forward proposals to the Company.

Shareholder(s) individually or jointly holding more than 3% of the shares of the Company may submit written provisional proposals to the convener 10 days before the general meeting. The convener shall serve a supplemental notice of the general meeting within two days after receipt of the provisional proposals and notify the contents of the said provisional proposals.

Save as specified in the preceding paragraph, the convener shall not change the proposals set out in the notice of the general meeting or add any new proposal after the said notice is served.

Proposals not set out in the notice of the general meeting or not complying with the Articles of Association shall not be voted on or resolved at the general meeting.

Board

The Board shall be responsible to the general meeting and shall exercise the following functions and powers in accordance with law:

(a) to convene general meetings and report to general meetings;

(b) to implement resolutions of general meetings;

(c) to resolve on the Company's business plans and investment plans;

(d) to prepare the annual financial budgets and final accounting plans of the Company;

(e) to prepare the profit distribution plan and loss makeup plan of the Company;

(f) to formulate proposals for the Company in respect of increase or reduction of registered capital, issue of bonds or other securities and the [**REDACTED**] thereof;

(g) to formulate plans for material acquisitions and purchase of shares of the Company;

(h) to formulate plans for merger, division, dissolution or transformation of the Company;

(i) to determine, within the authority granted by the general meeting, such matters as external investment, acquisition and disposal of assets, asset mortgage, external guarantee, consigned financial management, connected transactions, external financing, etc.;

(j) to approve the matters in relation to investment, acquisition or disposal of assets, financing and connected transactions as required by the listing rules of the stock exchange where the shares of the Company are [**REDACTED**];

(k) to decide on the establishment of internal management organizations of the Company;

(l) to appoint or dismiss the general manager and secretary to the Board of the Company; to appoint or dismiss senior management officers including deputy general manager(s) and the chief finance officer of the Company in accordance with the nominations by general manager, and to determine their remunerations, rewards and penalties;

(m) to set up the basic management system of the Company;

(n) to formulate the proposals for any amendment to the Articles of Association;

(o) to propose to the general meeting the appointment or replacement of the accounting firms which provide audit services to the Company;

(p) to listen to work reports of the general manager and review his/her work;

(q) to manage the information disclosure of the Company;

(r) to exercise other functions and powers as stipulated by laws, administrative regulations, department rules, regulatory rules of the place where the shares of the Company are [**REDACTED**] or the Articles of Association.

The Board may resolve on the issues specified in the above paragraphs by approval of more than half of the directors save for the issues specified in (f), (h) and (n), for which approval of more than two-thirds of the directors is required.

Board of Supervisors

The Board shall be responsible to the general meeting and shall exercise the following functions and powers in accordance with law:

(a) to check the financial condition of the Company and review the periodic reports of the Company prepared by the Board and express its written opinion;

(b) to monitor the performance of duties in the Company by directors and senior management and propose dismissal of directors and senior management who have violated laws, administrative regulations, the Articles of Association or the resolutions of general meetings;

(c) to require directors and the senior management to make corrections if their conduct has damaged the interests of the Company;

(d) to propose the convening of extraordinary general meetings and, in case the Board does not perform the obligations to convene and preside over the general meetings in accordance with Company Law, to convene and preside over the general meetings;

(e) to propose proposals to the general meetings;

(f) to initiate legal proceedings against directors and the senior management in accordance with laws;

(g) to conduct investigation if there is any doubt or any unusual circumstances in the Company's operations; and if necessary, to engage an accounting firm, law firm or other professional institutions to assist in their work at the expenses of the Company;

(h) to verify the financial information such as the financial report, business report and plans for distribution of profits to be submitted by the Board to the general meetings and, should any queries arise, to authorize, in the name of the Company, a re-examination by the certified public accountants and practising auditors of the Company for the time being; and

(i) Other functions and powers specified in the Articles of Association.

Secretary to the Board

The Company shall have a secretary to the Board, who shall be held by a natural person with requisite professional knowledge and experience, shall be appointed and dismissed by the Board and be the senior management of the Company.

The major duties of the secretary to the Board are:

(a) to ensure that the Company has complete organization documents and records;

(b) to ensure that the Company legally prepares and submits reports and documents as required by relevant competent authorities;

(c) to ensure that register of members of the Company is established appropriately, maintain the registers of the shareholders, directors and senior management and the documents and minutes of the general meeting, board meetings and meetings of special committees under the Board, and ensure that persons who are entitled to obtain the Company's records and documents can timely obtain the relevant records and documents;

(d) to organize and prepare board meetings and general meetings of shareholders, prepare meeting materials, arrange relevant meeting affairs, be responsible for meeting minutes, ensure the accuracy of the records, prepare and keep meeting documents and records, actively monitor the implementation of relevant resolutions, and report and make recommendations to the board of directors on important issues in implementation;

(e) to be responsible for matters pertaining to information disclosure of the Company, and ensure the timeliness, accuracy, lawfulness, authenticity and completeness of the Company's information disclosure;

(f) such other duties specified by the rules of the stock exchange in the place where the shares of the Company are [**REDACTED**].

A director or other senior management of the Company may also act as the secretary to the Board of the Company. Accountants of the accounting firm appointed by the Company shall not act as the secretary to the Board.

Where the office of secretary to the Board of the Company is held concurrently by a director, and an act is required to be done by a director and the secretary to the Board of the Company separately, the person who holds the office of director and secretary to the Board of the Company may not perform the act in a dual capacity.

Dispute resolutions

The Company shall abide by the following principles for dispute resolution:

(a) Whenever any disputes or claims of rights arise between: holders of the overseas [**REDACTED**] foreign shares and the Company; holders of the overseas [**REDACTED**] foreign shares and the Company's directors, supervisors, managing directors or other senior management; or holders of the overseas [**REDACTED**] foreign shares and holders of domestic shares, in respect of any rights or obligations as provided in the Articles of Association, the Company Law and other relevant laws and administrative regulations concerning the affairs of the Company, such disputes or claims shall be referred by the relevant parties to arbitration.

Where a dispute or claim referred to in the preceding paragraph is referred to arbitration, the entire claim or dispute must be referred to arbitration, and all persons who have a cause of action based on the same facts giving rise to the dispute or claim or whose participation is necessary for the resolution of such dispute or claim, shall, where such person is the Company, the shareholders, directors, supervisors, managing directors or other senior management of the Company, comply with the arbitration.

Disputes in respect of the definition of shareholders and disputes in relation to the register of members need not be resolved by arbitration.

(b) A claimant may elect for arbitration to be carried out at either the China International Economic and Trade Arbitration Commission in accordance with its Rules or the Hong Kong International Arbitration Centre in accordance with its Securities Arbitration Rules. Once a claimant refers a dispute or claim to arbitration, the other party must submit to the arbitral body elected by the claimant.

If a claimant elects for arbitration to be carried out at Hong Kong International Arbitration Centre, any party to the dispute or claim may apply for a hearing to take place in Shenzhen in accordance with the Securities Arbitration Rules of the Hong Kong International Arbitration Centre.

(c) If any disputes or claims of rights are settled by way of arbitration in accordance with paragraph (a), the laws of the PRC shall apply, save as otherwise provided in the laws, administrative regulations.

(d) The award of an arbitral body shall be final and conclusive and binding on all parties.

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Establishment of our Company

Our Company was established in the PRC on December 30, 2013 and was converted to a joint stock company with limited liability under the PRC Company Law with effect from March 29, 2021. Our Company has established a place of business in Hong Kong at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong, and was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on March 28, 2022. Ms. Lai Siu Kuen has been appointed as our agent for the acceptance of service of process and notices on behalf of our Company in Hong Kong.

As we are established in the PRC, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. A summary of the relevant provisions of our Articles of Association is set out in Appendix V to this document. A summary of certain relevant aspects of the laws and regulations of the PRC is set out in Appendix IV to this document.

2. Changes in the share capital of our Company

As of the date of our establishment, our registered capital was RMB10,000,000 which was fully paid up.

On December 9, 2020, our registered capital was increased from RMB10,000,000 to RMB360,000,000.

On December 16, 2020, our registered capital was increased from RMB360,000,000 to RMB407,560,000.

On January 18, 2021, our registered capital was increased from RMB407,560,000 to RMB464,852,146.2.

On January 28, 2021, our registered capital was increased from RMB464,852,146.2 to RMB483,199,497.01.

On March 29, 2021 our Company was converted from a limited liability company into a joint stock company with limited liability. The registered capital of our Company became RMB484,000,000 divided into 484,000,000 Shares with a nominal value of RMB1.00 each.

On September 15, 2021, our Company issued 14,583,294 Shares to the Series B Investors, upon which our share capital increased to RMB498,583,294, comprising 498,583,294 Shares with a nominal value of RMB1.00 each.

Assuming the [**REDACTED**] is not exercised, upon completion of the [**REDACTED**], our share capital will be increased to RMB[**REDACTED**], made up of [**REDACTED**] H Shares fully paid up or credited as fully paid up, representing 100% of our share capital. Save as aforesaid, there has been no alteration in our share capital since our establishment.

3. Restriction of share repurchase

For details of the restrictions on the share repurchase by our Company, please refer to "Summary of Articles of Association" in Appendix V to this document.

4. Resolutions of our Shareholders passed at our Company's extraordinary general meeting held on February 11, 2022

At the extraordinary general meeting of our Company held on February 11, 2022, among other things, the following resolutions were passed by the Shareholders:

(a) the issue by our H Shares with a nominal value of RMB1.00 each and such H Shares to be [**REDACTED**] on the Stock Exchange;

(b) subject to the completion of the [**REDACTED**], the Articles of Association has been approved and adopted, which shall only become effective on the [**REDACTED**], and our Board has been authorized to amend the Articles of Association in accordance with any comments from the Stock Exchange and the relevant PRC regulatory authorities; and

(c) authorizing our Board to handle all relevant matters relating to, among other things, the implementation of issue of H Shares and the [**REDACTED**].

5. Particulars of our subsidiaries

Set out below is certain information of our subsidiaries as of the Latest Practicable Date:

No.	Name of subsidiary	Identity of shareholder(s)/ member(s)	Direct/indirect percentage of ownership of our Company
1.	Boan Nanjing	Our Company	100%
2.	Boan Singapore	Our Company	100%
3.	Boan Boston	Boan Singapore	100%

6. Change in the registered capital of subsidiaries

Our Company's subsidiaries are referred to in the Accountant's Report in Appendix I to this document. Save for the subsidiaries mentioned above, in the Accountant's Report and the section headed "History, Development and Corporate Structure" in this document, our Company has no other subsidiaries.

Boan Singapore

On February 3, 2022, the issued capital of Boan Singapore was increased from US $1 to US $8,000,001.

Save as disclosed above, there has been no alteration in the share capital of any of our subsidiaries within the two years immediately preceding the date of this document.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of material contracts

We have entered into the following contracts (not being contracts entered into in the ordinary course of business) within the two years preceding the date of this document that are or may be material:

(a) a capital injection agreement (增資協議) dated December 19, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)) agreed to make a capital contribution of RMB100,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(b) a capital injection agreement (增資協議) dated December 22, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB30,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(c) a capital injection agreement (增資協議) dated December 23, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)) agreed to make a capital contribution of RMB10,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(d) a capital injection agreement (增資協議) dated December 28, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資有限公司), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資有限公司) agreed to make a capital contribution of RMB50,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(e) a capital injection agreement (增資協議) dated December 28, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian

Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)) agreed to make a capital contribution of RMB10,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(f) a capital injection agreement (增資協議) dated December 29, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB40,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(g) a capital injection agreement (增資協議) dated December 30, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合伙)), Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Qianhai Equity Investment Fund (Limited Partnership)) (前海股權投資基金(有限合伙)) and Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)) agreed to make a capital contribution of RMB70,000,000 and RMB30,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), respectively;

(h) a capital injection agreement (增資協議) dated December 30, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)) agreed to make a capital contribution of RMB10,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(i) a capital injection agreement (增資協議) dated December 30, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Serendipity Investment (Hong Kong) Limited, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Serendipity Investment (Hong Kong) Limited agreed to make a capital contribution in the aggregate amount of U.S. dollars equivalent to RMB65,256,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(j) a capital injection agreement (增資協議) dated December 30, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Asian Alliance (Hong Kong) Limited, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Asian Alliance (Hong Kong) Limited agreed to make a capital contribution in the aggregate amount of U.S. dollars equivalent to RMB6,525,600 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(k) a capital injection agreement (增資協議) dated December 31, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB60,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(l) a capital injection agreement (增資協議) dated December 31, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區博睿羅伊股權投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區博睿羅伊股權投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB30,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(m) a capital injection agreement (增資協議) dated December 31, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)) agreed to make a capital contribution of RMB20,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(n) a capital injection agreement (增資協議) dated December 31, 2020 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Advantech Capital Investment XIV Limited, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Advantech Capital Investment XIV Limited agreed to make a capital contribution in the aggregate amount of U.S. dollars equivalent to RMB150,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(o) a capital injection agreement (增資協議) dated January 19, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB10,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(p) a capital injection agreement (增資協議) dated January 25, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Jianyin Juyuan Investment Management (Beijing) Co., Ltd. (建銀聚源投資管理(北京)有限公司), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Jianyin Juyuan Investment Management (Beijing) Co., Ltd. (建銀聚源投資管理(北京)有限公司) agreed to make a capital contribution of RMB100,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(q) a capital injection agreement (增資協議) dated January 25, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB20,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(r) a capital injection agreement (增資協議) dated January 25, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Starr International Investments HK V, Limited, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Starr International Investments HK V, Limited agreed to make a capital contribution of US$10,000,000 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司);

(s) a shareholders agreement (股東協議) dated January 25, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)), Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合伙)), Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)), Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資有限公司), Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)), Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區博睿羅伊股權投資合伙企業(有限合伙)), Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)), Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)), Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)), Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)), Advantech Capital Investment XIV Limited, Serendipity Investment (Hong Kong) Limited, Asian Alliance (Hong Kong) Limited, Jianyin Juyuan Investment Management (Beijing) Co., Ltd. (建銀聚源投資管理(北京)有限公司), Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)), Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)), Starr International Investments HK V, Limited, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)), Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合伙)), Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)),

Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資有限公司), Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)), Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區博睿羅伊股權投資合伙企業(有限合伙)), Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)), Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)), Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)), Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)) Advantech Capital Investment XIV Limited, Serendipity Investment (Hong Kong) Limited, Asian Alliance (Hong Kong) Limited, Jianyin Juyuan Investment Management (Beijing) Co., Ltd. (建銀聚源投資管理(北京)有限公司), Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)), Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)) and Starr International Investments HK V, Limited agreed to make an aggregate capital contribution of RMB876,617,600 to Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術有限公司), of which RMB75,639,497.01 would be contributed to our registered capital and the remaining would be accounted as capital reserve;

(t) a capital injection agreement (增資協議) dated August 25, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Beijing GTJA Huike Venture Capital Partnership (Limited Partnership) (北京高特佳匯科創業投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Beijing GTJA Huike Venture Capital Partnership (Limited Partnership) (北京高特佳匯科創業投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB50,000,000 to Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司);

(u) a capital injection agreement (增資協議) dated August 25, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Yunnan Felix Equity Investment Fund Management Partnership (Limited Partnership) (雲南菲利克斯股權投資基金管理合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Yunnan Felix Equity Investment Fund Management Partnership (Limited Partnership) (雲南菲利克斯股權投資基金管理合伙企業(有限合伙)) agreed to make a capital contribution of RMB40,000,000 to Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司);

(v) a capital injection agreement (增資協議) dated September 13, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Advantech Capital Investment XIV Limited, Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Advantech Capital Investment XIV Limited agreed to make a capital contribution of US$2,000,000 to Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司);

(w) a capital injection agreement (增資協議) dated September 13, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)) agreed to make a capital contribution of RMB8,000,000 to Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司);

(x) a capital injection agreement (增資協議) dated September 13, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), Shandong New Growth Drivers Fund Management Co., Ltd. (山東省新動能基金管理有限公司), Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Shandong New Growth Drivers Fund Management Co., Ltd. (山東省新動能基金管理有限公司) agreed to make a capital contribution of RMB100,000,000 to Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司);

(y) a shareholders agreement (股東協議) dated September 13, 2021 entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)), Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合伙)), Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)), Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資

有限公司), Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)), Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited Partnership) (寧波梅山保税港區博睿羅伊股權投資合伙企業(有限合伙)), Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)), Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)), Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)), Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)), Advantech Capital Investment XIV Limited, Serendipity Investment (Hong Kong) Limited, Asian Alliance (Hong Kong) Limited, Jianyin Juyuan Investment Management (Beijing) Co.,Ltd. (建銀聚源投資管理(北京)有限公司), Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)), Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)), Starr International Investments HK V, Limited, Beijing GTJA Huike Venture Capital Partnership (Limited Partnership) (北京高特佳匯科創業投資合伙企業(有限合伙)), Yunnan Felix Equity Investment Fund Management Partnership (Limited Partnership) (雲南菲利克斯股權投資基金管理合伙企業(有限合伙)) and Shandong New Growth Drivers Fund Management Co., Ltd. (山東省新動能基金管理有限公司), Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which Beijing GTJA Huike Venture Capital Partnership (Limited Partnership) (北京高特佳匯科創業投資合伙企業(有限合伙)), Yunnan Felix Equity Investment Fund Management Partnership (Limited Partnership) (雲南菲利克斯股權投資基金管理合伙企業(有限合伙)), Shandong New Growth Drivers Fund Management Co., Ltd. (山東省新動能基金管理有限公司), Advantech Capital Investment XIV Limited and Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)) agreed to subscribe for 14,583,294 shares of Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司) at a total consideration of RMB210,915,400;

(z) a shareholders' special rights termination agreement (股東特殊權利條款終止協議) dated March 1, 2022, entered into among Shandong Luye Pharmaceutical Co., Ltd. (山東綠葉製藥有限公司), SIP Sungent BioVenture Venture Capital Investment Partnership III (Limited Partnership) (蘇州工業園區新建元三期創業投資企業(有限合伙)), Shenzhen BioResearch Investment Fund Limited Partnership (Limited Partnership) (深圳市柏奧瑞思投資合伙企業(有限合伙)), Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合伙)), Qingdao Brill Aimei Investment Partnership (Limited Partnership) (青島博睿愛美投資合伙企業(有限合伙)), Yantai Blue Ocean Venture Capital Co., Ltd. (煙台市藍海創業投資有限公司), Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資基金(有限合伙)), Ningbo Meishan Free Trade Port District Brill Luoyi Equity Investment Partnership (Limited

Partnership) (寧波梅山保税港區博睿羅伊股權投資合伙企業(有限合伙)), Shenzhen Qianhai Weiyang Investment Center (Limited Partnership) (深圳前海維陽投資中心(有限合伙)), Yantai Innovative Technology New Growth Drivers Investment Center (Limited Partnership) (煙台創科新動能投資中心(有限合伙)), Nanjing Ruiyuan Investment Management Partnership (Limited Partnership) (南京瑞源投資管理合伙企業(有限合伙)), Shenzhen Xingrui Investment Center (Limited Partnership) (深圳興銳投資中心(有限合伙)), Advantech Capital Investment XIV Limited, Serendipity Investment (Hong Kong) Limited, Asian Alliance (Hong Kong) limited, Jianyin Juyuan Investment Management (Beijing) Co., Ltd. (建銀聚源投資管理(北京)有限公司), Yantai Wensen Investment Partnership (Limited Partnership) (煙台文森投資合伙企業(有限合伙)), Yantai Bohui Investment Partnership (Limited Partnership) (煙台伯匯投資合伙企業(有限合伙)), Starr International Investments HK V, Limited, Beijing GTJA Huike Venture Capital Partnership (Limited Partnership) (北京高特佳匯科創業投資合伙企業(有限合伙)), Yunnan Felix Equity Investment Fund Management Partnership (Limited Partnership) (雲南菲利克斯股權投資基金管理合伙企業(有限合伙)), Shandong Growth Drivers Jiazhi Asset Investment Fund Partnership (Limited Partnership) (山東動能嘉智產業投資基金合伙企業(有限合伙)), Shandong Boan Biotechnology Co., Ltd. (山东博安生物技术股份有限公司), Yantai Bofa Investment Center (Limited Partnership) (煙台博發投資中心(有限合伙)), Yantai Bosheng Investment Center (Limited Partnership) (煙台博晟投資中心(有限合伙)), Yantai Bolian Investment Center (Limited Partnership) (煙台博聯投資中心(有限合伙)) and Luye Pharma Group Ltd., pursuant to which certain shareholders' special rights were terminated and will cease to have any effect upon [**REDACTED**];

(aa) the Deed of Indemnity; and

(bb) the [**REDACTED**].

2. Intellectual property rights of our Group

(a) Trademarks

As of the Latest Practicable Date, our Group was the registered proprietor of the following trademarks which, in the opinion of our Directors, are material to our business:

No.	Trademark	Registration number	Class	Name of Registered Proprietor	Place of Registration	Date of Registration	Expiry Date
1.		40486520	5	Our Company	PRC	December 28, 2020	December 27, 2030
2.		305836717	5	Our Company	Hong Kong	December 20, 2021	December 19, 2031
3.		305836816	5	Our Company	Hong Kong	December 20, 2021	December 19, 2031
4.	博优诺	42751727	5	Our Company	PRC	August 28, 2020	August 27, 2030
5.	博优倍	42748189	5	Our Company	PRC	August 28, 2020	August 27, 2030
6.	BAhMab	55379975	42	Our Company	PRC	October 28, 2021	October 27, 2031
7.	BAhuMab	55392304	42	Our Company	PRC	October 28, 2021	October 27, 2031
8.	BAhuMab	305749237	42	Our Company	Hong Kong	September 17, 2021	September 16, 2031
9.	BA-huMab	1659134	42	Our Company	Russia, Australia, European Union and United Kingdom	February 21, 2022	February 20, 2032
10.	BAhuMab	1629903	42	Our Company	Mexico	September 17, 2021	September 16, 2031
11.	BA-huMab	305887603	42	Our Company	Hong Kong	February 22, 2022	February 21, 2032
12.	BA-huMab	62187491	42	Our Company	PRC	July 14, 2022	July 13, 2031
13.	BAhuMab3	55386737	42	Our Company	PRC	October 28, 2021	October 27, 2031
14.	BAhuMabIII	55381940	42	Our Company	PRC	October 28, 2021	October 27, 2031

No.	Trademark	Registration number	Class	Name of Registered Proprietor	Place of Registration	Date of Registration	Expiry Date
15.	Boyounuo	57941657	5	Our Company	PRC	January 28, 2022	January 27, 2032
16.	Boyounuo	1621170	5	Our Company	European Union, United Kingdom, Philippines, Indonesia and Singapore	August 19, 2021	August 18, 2031
17.	Boyoubei	1636139	5	Our Company	Philippines	November 8, 2021	November 7, 2031
18.	Boyoubei	59766387	5	Our Company	PRC	April 7, 2022	April 6, 2032
19.	安得平	58223364	5	Our Company	PRC	January 28, 2022	January 27, 2032
20.	葆可利	58209065	5	Our Company	PRC	January 28, 2022	January 27, 2032
21.	葆可悦	58213918	5	Our Company	PRC	January 28, 2022	January 27, 2032
22.	博利吉	58223345	5	Our Company	PRC	January 28, 2022	January 27, 2032
23.	博利寿	58223335	5	Our Company	PRC	January 28, 2022	January 27, 2032
24.	博洛加	58202456	5	Our Company	PRC	January 28, 2022	January 27, 2032
25.	博优贺	58207246	5	Our Company	PRC	January 28, 2022	January 27, 2032
26.	博优欢	58226078	5	Our Company	PRC	January 28, 2022	January 27, 2032
27.	博优景	58226072	5	Our Company	PRC	January 28, 2022	January 27, 2032
28.	博优天	58215250	5	Our Company	PRC	January 28, 2022	January 27, 2032
29.	STEALTH CAR-T	52324128	5	Boan Nanjing	PRC	August 28, 2021	August 27, 2031
30.	ReceptorTAC	52316075	5	Boan Nanjing	PRC	August 21, 2021	August 20, 2031
31.	CAR-BiTE	52330814	5	Boan Nanjing	PRC	August 14, 2021	August 13, 2031

As of the Latest Practicable Date, our Group was granted a license to the use of the following trademark which, in the opinion of our Directors is material to our business:

No.	Trademark	Registration number	Class	Name of registered proprietor	Place of registration	Date of registration	Expiry date
1.		304792816	5, 35	Shandong Luye	Hong Kong	January 7, 2019	January 6, 2029

As of the Latest Practicable Date, we had applied for the registration of the following trademarks which, in the opinion of our Directors, material to our business:

No.	Trademark	Application Number	Class	Applicant	Place of Application	Application Date
1.	Boyounuo	90897779	5	Our Company	U.S.	August 23, 2021
2.	Boyounuo	1621170	5	Our Company	Vietnam, Thailand and Malaysia	August 19, 2021
3.	BAhuMab	97055156	42	Our Company	U.S.	September 30, 2021
4.	BAhuMab	1629903	42	Our Company	Algeria, Egypt, Kazakhstan, Russia, Vietnam, Australia, Columbia, European Union, United Kingdom, India, Japan, Korea, Philippines, Turkey, Indonesia, Canada, Brazil and Pakistan	September 17, 2021

No.	Trademark	Application Number	Class	Applicant	Place of Application	Application Date
5.	BA-huMab	97277274	42	Our Company	U.S.	February 21, 2022
6.	BA-huMab	1659134	42	Our Company	Algeria, Egypt, Kazakhstan, Vietnam, Colombia, India, Japan, Korea, Mexico, Philippines, Turkey, Indonesia, Canada, Brazil and Pakistan	February 21, 2022
7.	Boyoubei	97118717	5	Our Company	U.S.	November 10, 2021
8.	Boyoubei	1636139	5	Our Company	Vietnam, European Union, United Kingdom, Singapore, Thailand, Indonesia and Malaysia	November 8, 2021
9.	STEALTH CAR-T	90760499	5	Boan Nanjing	U.S.	June 8, 2021
10.	ReceptorTAC	90760515	5	Boan Nanjing	U.S.	June 8, 2021

(b) Patents

As of the Latest Practicable Date, our Group had registered the following patents which, in the opinion of our Directors, are material to our business:

No.	Patent	Type	Patent Number	Registered Owner	Place of Registration	Date of Application	Status
1.	A preparation method of transgenic animal expressing human antibody (一種能夠表達人抗體的轉基因動物的製備方法)	Invention	ZL201210281415.1	Our Company	PRC	August 9, 2012	Granted

No.	Patent	Type	Patent Number	Registered Owner	Place of Registration	Date of Application	Status
2.	Amphiphilic block copolymer micelles of macromolecules of biologically functional protein and preparation and application thereof (生物功能性蛋白大分子的兩親嵌段共聚物膠束及其製備和應用)	Invention	ZL201210455274.0	Our Company	PRC	November 13, 2012	Granted
3.	Purification of protein by cation exchange chromatography (利用陽離子交換層析純化蛋白質)	Invention	ZL201410359482.X	Our Company	PRC	July 25, 2014	Granted
4.	A purification method of VEGF capture agent fusion protein (VEGF捕獲劑融合蛋白的純化方法)	Invention	ZL201711346802.8	Our Company	PRC	December 15, 2017	Granted
5.	A purification method of recombinant fusion protein by linear elution (採用線性洗脫步驟的重組融合蛋白純化方法)	Invention	ZL201711351111.7	Our Company	PRC	December 15, 2017	Granted
6.	Anti-PD-L1 antibody and use thereof (抗PD-L1的抗體及其用途)	Invention	ZL201880055538.9	Our Company	PRC	November 26, 2018	Granted
7.	A kind of anti-4-1BB antibody, composition containing same and application thereof (一種抗4-1BB抗體、含有其的組合物及其應用)	Invention	ZL201911029988.3	Our Company	PRC	October 28, 2019	Granted
8.	An antibody that specifically binds to human 4-1BB and application thereof (一種特異性結合人4-1BB的抗體及其應用)	Invention	ZL201911030208.7	Our Company	PRC	October 28, 2019	Granted
9.	Anti-ANGPTL3 antibody and use thereof (抗ANGPTL3抗體及其用途)	Invention	ZL202010446335.1	Our Company	PRC	May 25, 2020	Granted
10.	ANGPTL3 binding fragments and use thereof (ANGPTL3結合片段及其用途)	Invention	ZL202010446346.X	Our Company	PRC	May 25, 2020	Granted
11.	LAG3-binding fragments and use thereof (LAG3結合片段及其用途)	Invention	ZL202010446621.8	Our Company	PRC	May 25, 2020	Granted
12.	CD47 antagonists and use thereof (CD47拮抗劑及其用途)	Invention	ZL202010461205.5	Our Company	PRC	May 27, 2020	Granted

No.	Patent	Type	Patent Number	Registered Owner	Place of Registration	Date of Application	Status
13.	Anti-LAG3 antibody and use thereof (抗LAG3抗體及其用途)	Invention	ZL202010446631.1	Our Company	PRC	May 25, 2020	Granted
14.	Anti-CD47 monoclonal antibody and application thereof (抗CD47單克隆抗體及其應用)	Invention	ZL202010461195.5	Our Company	PRC	May 27, 2020	Granted
15.	Anti-Interleukin-4 receptor (IL-4R) antibody and application thereof (抗白介素4受體(IL-4R)的抗體及其應用)	Invention	ZL202010464384.8	Our Company	PRC	May 27, 2020	Granted
16.	Interleukin-4 receptor (IL-4R) recombinant protein and its application (白介素4受體(IL-4R)結合蛋白及其用途)	Invention	ZL202010464386.7	Our Company	PRC	May 27, 2020	Granted
17.	Antibody or chimeric antigen receptor which targets Claudin 18.2 (靶向Claudin 18.2的抗體或嵌合抗原受體)	Invention	ZL202080000840.1	Our Company	PRC	May 28, 2020	Granted
18.	Anti-CGRP antibody and application thereof (抗CGRP抗體及其應用)	Invention	ZL202080000851.X	Our Company	PRC	May 28, 2020	Granted
19.	Bifunctional fusion protein against PDL1 and TGFβ and use thereof (抗PDL1和TGFβ的雙功能融合蛋白及其用途)	Invention	ZL202080000954.6	Our Company	PRC	June 8, 2020	Granted
20.	Anti-CD25 antibody and application thereof (抗CD25抗體及其應用)	Invention	ZL202080000963.5	Our Company	PRC	June 8, 2020	Granted
21.	Anti-β-NGF nano antibody and application thereof (抗β-NGF納米抗體及其應用)	Invention	ZL202080000967.3	Our Company	PRC	June 8, 2020	Granted
22.	Neutralizing antibody of SARS-CoV-2 virus and application thereof (SARS-CoV-2病毒的中和抗體及其應用)	Invention	ZL202180003751.7	Our Company	PRC	June 3, 2021	Granted
23.	A kind of anti-FGL1 antibody and use thereof (一種抗FGL1抗體及其用途)	Invention	ZL202210454764.2	Our Company	PRC	April 28, 2022	Granted
24.	A kind of ROR1 antibody or antigen-binding fragment thereof (一種ROR1抗體或其抗原結合片段)	Invention	ZL202210425699.0	Our Company	PRC	April 29, 2022	Granted

As of the Latest Practicable Date, our Group had applied for the registration of the following patents which, in the opinion of our Directors, are material to our business:

No.	Patent	Type	Application Number	Name of Applicant	Place(s) of Application	Date of Application
1.	A 500L-scale cell culture method for producing monoclonal antibodies (一種500L規模細胞培養生產單抗的方法)	Invention	CN202111106580.9	Our Company	PRC	September 22, 2021
2.	A 2000L-scale cell culture method for producing monoclonal antibodies (一種2000L規模細胞培養生產單抗的方法)	Invention	CN202111114231.1	Our Company	PRC	September 23, 2021
3.	Optimized Anti-CD3 arm in the generation of T-cell bispecific antibodies for immunotherapy	Invention	PCT/CN2020/136452	Our Company	PCT	December 15, 2020
4.	Neutralizing antibody of SARS-CoV-2 virus and application thereof (SARS-CoV-2病毒的中和抗體及其應用)	Invention	PCT/CN2021/098077	Our Company	PCT	June 3, 2021
5.	A method to treat or prevent the disease caused by the new coronavirus SARS-CoV-2 (一種治療或預防新型冠狀病毒SARS-CoV-2引起的疾病的方法)	Invention	PCT/CN2021/121556	Our Company	PCT	September 29, 2021

(c) **Domain name**

As of the Latest Practicable Date, our Group was the registered proprietor of the following domain name in the PRC which, in the opinion of our Directors, is material to our business:

Domain Name	Name of Registered Proprietor	Date of Registration	Expiry Date
www.boan-bio.com	Our Company	November 3, 2020	January 4, 2026

C. FURTHER INFORMATION ABOUT DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Directors and Supervisors

(a) Interests and short positions of the Directors, Supervisors and the chief executive of our Company in the registered capital of our Company and its associated corporations

Immediately following the completion of the [**REDACTED**] and assuming that the [**REDACTED**] is not exercised, the interests or short positions of Directors, Supervisors or chief executive of our Company in the Shares, underlying Shares and debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will be required to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests or short positions which they were taken or deemed to have under such provisions of the SFO) or which will be required, under Section 352 of the SFO, to be entered in the register referred to in that section, or which will be required, under the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules (the "**Model Code**"), to be notified to our Company once the H Shares are [**REDACTED**] will be as follows:

Interest in our Company

Name	Nature of Interest	Class of Shares	Number of Shares[(1)]	Approximate percentage holding in the total issued share capital
Ms. Jiang Hua	Interest in a controlled corporation[(2)(3)(4)]	H Shares	[REDACTED] (L)	[REDACTED]

Name	Nature of Interest	Class of Shares	Number of Shares[(1)]	Approximate percentage holding in the total issued share capital
Dr. Dou Changlin	Interest in a controlled corporation[(2)]	H Shares	[**REDACTED**] (L)	[**REDACTED**]
Dr. Li Youxin	Interest in a controlled corporation[(2)]	H Shares	[**REDACTED**] (L)	[**REDACTED**]
Mr. Liu Yuanchong	Interest in a controlled corporation[(2)(3)(4)]	H Shares	[**REDACTED**] (L)	[**REDACTED**]
Ms. Li Li	Interest in a controlled corporation[(2)(3)(4)]	H Shares	[**REDACTED**] (L)	[**REDACTED**]

Notes:

(1) The letter "L" denotes a long position in our Shares.

(2) Immediately prior to and following the completion of the [**REDACTED**], Yantai Bolian will hold [**REDACTED**] Shares, representing approximately [**REDACTED**] of our Shares in issue (without taking into account Shares which may be issued pursuant to the exercise of the [**REDACTED**]). Ms. Li is the general partner of Yantai Bolian and is therefore deemed to be interested in the Shares held by Yantai Bolian. As part of our employee share incentive plan, pursuant to the partnership agreement among its partners, Yantai Bolian will hold [**REDACTED**], [**REDACTED**] and [**REDACTED**] Shares upon completion of the [**REDACTED**] on behalf of Ms. Jiang, Dr. Dou and Dr. Li, respectively, who were deemed to be interested to these respective Shares held by Yantai Bolian.

(3) Immediately prior to and following the completion of the [**REDACTED**], Yantai Bofa will hold [**REDACTED**] Shares, representing approximately [**REDACTED**] of our Shares in issue (without taking into account Shares which may be issued pursuant to the exercise of the [**REDACTED**]). Ms. Li is the general partner of Yantai Bofa and is therefore deemed to be interested in the Shares held by Yantai Bofa. As part of our employee share incentive plan, pursuant to the partnership agreement among its partners, Yantai Bofa will hold [**REDACTED**] and [**REDACTED**] Shares upon completion of the [**REDACTED**] on behalf of Ms. Jiang and Mr. Liu, respectively, who were deemed to be interested to these respective Shares held by Yantai Bofa.

(4) Immediately prior to and following the completion of the [**REDACTED**], Yantai Bosheng will hold [**REDACTED**] Shares, representing approximately [**REDACTED**] of our Shares in issue (without taking into account Shares which may be issued pursuant to the exercise of the [**REDACTED**]). Ms. Li is the general partner of Yantai Bosheng and is therefore deemed to be interested in the Shares held by Yantai Bosheng. As part of our employee share incentive plan, pursuant to the partnership agreement among its partners, Yantai Bosheng will hold [**REDACTED**] and [**REDACTED**] Shares upon completion of the [**REDACTED**] on behalf of Ms. Jiang and Mr. Liu, respectively, who were deemed to be interested to these respective Shares held by Yantai Bosheng.

(b) Particulars of service agreements and letters of appointment

Each of our Directors and Supervisors entered into a service contract or appointment letter with our Company. The principal particulars of these service contracts and appointment letters comprise (a) the term of the service; (b) subject to termination in accordance with their respective term; and (c) a dispute resolution provision. The service contracts and appointment letters may be renewed in accordance with our Articles of Association and the applicable laws, rules and regulations from time to time.

Save as disclosed above, none of our Directors or Supervisors has or is proposed to have a service contract with any member of our Group (other than contracts expiring or determinable by the relevant employer within one year without the payment of compensation (other than statutory compensation)).

(c) Directors' and Supervisors' remuneration

Each of our executive Directors, being Ms. Jiang Hua and Dr. Dou Changlin, is entitled to receive a director's fee to be determined annually by the Board based on their performance. The aggregate remuneration (including fees, salaries, allowances and benefits in kind, performance-related bonuses, pension scheme contributions and equity-settled share-based payments) paid to our Directors and Supervisors for the years ended December 31, 2020 and 2021 and the six months ended June 30, 2022 was approximately RMB2.08 million, RMB19.53 million and RMB8.97 million, respectively. For details, please refer to Note 8 to the Accountants' Report as set out in Appendix I to this document.

Each of our non-executive Directors, namely, Dr. Li Youxin, Mr. Liu Yuanchong, Ms. Li Li and Mr. Chen Jie is not expected to receive any remuneration for holding their office as non-executive Directors.

We intend to pay a director's fee of RMB100,000 per annum to each of our independent non-executive Directors, being Mr. Liu Zhengjun, Mr. Shi Luwen and Mr. Dai Jixiong. Save for directors' fees, none of our independent non-executive Directors is expected to receive any other remuneration for holding their office as independent non-executive Directors.

Our employee representative Supervisor, Ms. Ning Xia, is entitled to receive a supervisor's fee to be determined annually by our Board based on her performance. Save for Ms. Ning Xia, our Supervisors are not expected to receive any remuneration for holding their office as Supervisors. Save for supervisor's fees, none of our Supervisors is expected to receive any other remuneration for holding their office as Supervisors.

Under the arrangements currently in force as of the date of this document, the aggregate remuneration (including fees, salaries, allowances and benefits in kind, performance related bonuses, pension scheme contributions and equity-settled share-based payment) of our Directors and Supervisors from our Company for the year ending December 31, 2022 is estimated to be no more than approximately RMB6.67 million.

2. Substantial Shareholders

Save as disclosed in the section headed "Substantial Shareholders" in this document, our Directors are not aware of any person (other than our Director or chief executive of our Company) who will, immediately following completion of the [**REDACTED**] (assuming that the [**REDACTED**] is not exercised), have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

3. Agency fees or commissions received

Save as disclosed in this section, none of our Directors, Supervisors or any of the persons whose names are listed under "— D. Other information — 8. Consents of experts" in this Appendix had received any commissions, discounts, agency fee, brokerages or other special terms in connection with the issue or sale of any capital of any member of our Group within the two years immediately preceding the date of this document.

4. Disclaimers

(a) none of our Directors or Supervisors nor any of the parties listed in "— D. Other information — 8. Consent of experts" in this Appendix has any direct or indirect interest in the promotion of our Company, or in any assets which within the two years immediately preceding the date of this document, have been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;

(b) save as disclosed in this section, none of our Directors or Supervisors is a director or employee of a company which is expected to have an interest in the Shares falling to be disclosed to our Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO once the H Shares are [**REDACTED**] on the Stock Exchange;

(c) none of our Directors or Supervisors nor any of the parties listed in "— D. Other information — 8. Consents of experts" in this Appendix, is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group as a whole;

(d) save for the [**REDACTED**], none of the parties listed in "— D. Other Information — 8. Consent of experts" in this Appendix:

(i) is interested legally or beneficially in any of our Shares or any shares of any of our subsidiaries; or

(ii) has any right or option (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe securities in any member of our Group;

(e) save as disclosed in this document, none of our Directors, Supervisors, their respective associates or Shareholders of our Company (who is interested in more than 5% of the share capital of our Company) has any interests in any of our top five suppliers and top five customers; and

(f) none of our Directors is interested in any business (other than the business of our Group) which competes or is likely to compete, directly or indirectly, with our business.

D. OTHER INFORMATION

1. Estate duty

Our Directors have been advised that currently no material liability for estate duty is likely to fall upon our Company in the PRC.

2. Tax and other indemnities

Our Controlling Shareholders [have] entered into the Deed of Indemnity with and in favor of our Company (for ourselves and as trustee for each of our subsidiaries) to provide indemnities on a joint and several basis in respect of, among other matters, (i) any liability for estate duty under the Estate Duty Ordinance (Chapter 111 of the Laws of Hong Kong), or legislation similar thereto in Hong Kong or any jurisdictions outside Hong Kong which might be incurred by any member of our Group on or before the [**REDACTED**]; (ii) any additional tax demand, late charges or penalties incurred after the [**REDACTED**] arising from any unreported tax, outstanding tax payment and any other tax liabilities resulting from any breach of applicable laws or regulations in the relevant jurisdiction by any member of our Group on or before the [**REDACTED**]; and (iii) any claims, penalties or other indebtedness resulting from any insufficient contribution to social insurance and housing provident funds during the Track Record Period save for (a) to the extent that sufficient provision or reserve has been made for such taxation or non-compliance incident in the audited consolidated financial statements of our Group as set out in Appendix I to this document; (b) to the extent that the liability for such taxation would not have arisen but for any act or omission of, or delay by, any member of our Group after the [**REDACTED**] without the prior written consent or agreement of our Controlling Shareholders, unless such act or omission is conducted or agreed upon in the ordinary course of business of our Group or under a legally binding obligation created on or before

the [**REDACTED**]; and (c) to the extent such loss arises or is incurred only as a result of a retrospective change in law or regulations or the interpretation or practice thereof by any relevant authority coming into force after the [**REDACTED**].

3. Litigation

We are not aware of any material legal proceedings, claims or disputes currently existing or pending against us, and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened against us that may have a material adverse effect on our business, financial position or results of operations.

4. Joint Sponsors

The Joint Sponsors have applied to the Stock Exchange for the [**REDACTED**] of, and permission to deal in, our H Shares to be issued pursuant to the [**REDACTED**] (including the additional H Shares which may be issued pursuant to the exercise of the [**REDACTED**]).

The Joint Sponsors satisfy the independence criteria applicable to sponsor set out in Rule 3A.07 of the Listing Rules.

The Joint Sponsors will receive an aggregate fee of [**REDACTED**] for acting as the Joint Sponsors for the [**REDACTED**].

5. Preliminary expenses

Our Company has not incurred any preliminary expenses for the purpose of the Listing Rules.

6. Promoters

The promoters of our Company are Shandong Luye, Yantai Bolian, Yantai Bosheng, Yantai Bofa and the Series A Investors.

Save as disclosed in the section headed "History, Development and Corporate Structure" in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters in connection with the [**REDACTED**] and the related transactions described in this document.

7. Qualification of experts

The following are the qualifications of the experts who have given opinion or advice which are contained in this document:

Name	Qualifications
UBS Securities Hong Kong Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 6 (advising on corporate finance) and Type 7 (providing automated trading services) regulated activities as defined under the SFO
Essence Corporate Finance (Hong Kong) Limited	Licensed under the SFO to conduct Type 1 (dealing in securities) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
Ernst & Young	Certified Public Accountants and Public Interest Entity Auditor registered in accordance with the Financial Reporting Council Ordinance
Commerce & Finance Law Offices	PRC Legal Adviser to our Company
Frost & Sullivan	Industry consultant

8. Consents of experts

Each of the experts named in paragraph 7 of this Appendix has given and has not withdrawn its respective written consent to the issue of this document with the inclusion of its report and/or letter and/or opinion and/or the references to its name included in this document the form and context in which it is respectively included.

9. Interests of experts in our Company

None of the persons named in paragraph 7 of this Appendix is interested beneficially or otherwise in any Shares or shares of any member of our Group or has any right or option (whether legally enforceable or not) to subscribe for or nominate persons to subscribe for any shares or securities in any member of our Group.

10. Taxation of holders of H Shares

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty. The current rate chargeable on each of the seller and purchaser is 0.13% of the consideration or, if higher, the fair value of the H Shares being sold or transferred.

11. Binding effect

This document shall have the effect, if an application is made in pursuance of this document, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance insofar as applicable.

12. Miscellaneous

(a) Saved as disclosed in this document, within the two years immediately preceding the date of this document:

(i) no share or loan capital of our Company or any of our subsidiaries has been issued or agreed to be issued or is proposed to be fully or partly paid either for cash or a consideration other than cash;

(ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;

(iii) no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries; and

(iv) no commission has been paid or is payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of any share in our Company or any of our subsidiaries.

(b) our Directors confirm that:

(i) there has been no material adverse change in the financial or trading position or prospects of our Group since June 30, 2022 (being the date to which the latest audited consolidated financial statements of our Group were prepared); and

(ii) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document;

(c) there are no founder, management or deferred shares nor any debentures in our Company or any of our subsidiaries;

(d) all necessary arrangements have been made to enable our H Shares to be admitted into [**REDACTED**] for clearing and settlement;

(e) no company within our Group is presently [**REDACTED**] on any stock exchange or traded on any trading system;

(f) our Company has no outstanding convertible debt securities or debentures;

(g) there is no arrangement under which future dividends are waived or agreed to be waived; and

(h) none of the equity and debt securities of our Company, if any, is [**REDACTED**] or dealt with in any other stock exchange nor is any [**REDACTED**] or permission to deal being or proposed to be sought.

13. Bilingual document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

A. DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to the copy of this document delivered to the Registrar of Companies in Hong Kong for registration were:

(a) a copy of the [**REDACTED**];

(b) the written consents referred to in "Statutory and General Information — D. Other information — 8. Consents of experts" in Appendix VI to this document; and

(c) a copy of each of the material contracts referred to in "Statutory and General Information — B. Further information about our business — 1. Summary of material contracts" in Appendix VI to this document.

B. DOCUMENTS ON DISPLAY

The following documents will be published on the websites of the Stock Exchange (**www.hkexnews.hk**) and our Company (**www.boan-bio.com**) up to and including the date which is 14 days from the date of this document:

(a) the Articles of Association;

(b) the Accountants' Report from Ernst & Young, the text of which is set out in Appendix I to this document;

(c) the report from Ernst & Young in respect of the unaudited pro forma financial information, the text of which is set out in Appendix II to this document;

(d) the audited consolidated financial statements of our Group for the two years ended December 31, 2020 and 2021 and the six months ended June 30, 2022;

(e) the material contracts referred to in "Statutory and General Information — B. Further Information about our business — 1. Summary of material contracts" in Appendix VI to this document;

(f) the service contracts referred to in "Statutory and General Information — C. Further information about Directors, Supervisors and substantial shareholders — 1. Directors and Supervisors — (b) Particulars of service agreements and letters of appointment" in Appendix VI to this document;

(g) the legal opinion issued by Commerce & Finance Law Offices, our legal adviser as to PRC law, in respect of certain general corporate matters and our Group's business operations in the PRC;

(h) the written consents referred to "Statutory and General Information — D. Other information — 8. Consent of experts" in Appendix VI to this document;

(i) the PRC Company Law, the PRC Securities Law, the Mandatory Provisions and the Special Regulations together with their unofficial English translation; and

(j) the Frost & Sullivan Report.