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Application Proof of

WUHAN YZY BIOPHARMA CO., LTD. 武漢友芝友生物製藥股份有限公司

(the “Company”)

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

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友芝友生物製藥

WUHAN ZYBIO PHARMA CO., LTD. 武漢友芝友生物製藥股份有限公司

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

[REDACTED]

Number of [REDACTED] under : [REDACTED] H Shares (subject to the the [REDACTED] [REDACTED])

Number of [REDACTED] : [REDACTED] H Shares (subject to reallocation)

Number of [REDACTED] : [REDACTED] H Shares (subject to [REDACTED] and the [REDACTED])

Maximum [REDACTED] : HK\$[REDACTED] per H Share, plus brokerage of 1.0%, SFC transaction levy of 0.0027%, AFRC transaction levy of 0.00015% and Stock Exchange trading fee of 0.00565% (payable in full on application in Hong Kong dollars and subject to refund)

Nominal value : RMB1.00 per H Share

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EXPECTED TIMETABLE

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SUMMARY

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 carefully before you decide to invest in the [REDACTED]. In particular, we are a biotechnology company seeking a [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. Moreover, 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.” You should read that section carefully.

OVERVIEW

Founded in 2010, we are a biotechnology company dedicated to developing bispecific antibody (BsAb)-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. We have designed and developed a pipeline of seven clinical-stage drug candidates, including (i) our Core Product M701, a recombinant BsAb that targets human epithelial cell adhesion molecule (EpCAM)-expressing cancer cells and human cluster of differentiation 3 (CD3)-expressing T cells. We are currently conducting a Phase II clinical trial of M701 in treating malignant ascites (MA) and a Phase Ib/II clinical trial of M701 in treating malignant pleural effusion (MPE), (ii) M802 and Y150, T cell-engaging BsAbs for cancer treatment, (iii) Y101D and Y332, tumor microenvironment (TME)-targeted BsAbs, (iv) Y400, a targeted therapy for the treatment of age-related ophthalmologic diseases, and (v) Y2019, a COVID-19 vaccine. We have strategically developed proprietary technology platforms, including YBODY® platform, Check-BODY platform and Nano-YBODY™ platform to support the R&D of our BsAbs.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP OR MARKET OUR CORE PRODUCT OR ANY OF OUR PIPELINE PRODUCTS.

Pipeline of Drug Candidates

We have designed and developed a pipeline of seven clinical-stage drug candidates. We carefully select potential targets for our drug candidates, and focus on the therapeutic areas with market potentials where fewer market players have expertise and resources. In particular,

- We have strategically focused on the development of the T cell-engaging BsAbs. We have developed three T cell-engaging BsAbs, namely M701, M802 and Y150;
- We have adopted the therapeutic strategy towards the efficient targeting of tumor microenvironment (TME). TME plays a critical role in tumor initiation, development and progression, and therefore is becoming an emerging treatment target for cancer. We are developing two drug candidates targeting TME, namely Y101D and Y332;
- We are developing Y400, a targeted therapy for the treatment of age-related ophthalmologic diseases.

Our R&D efforts focus on the development of BsAbs. A BsAb is an artificial protein that recognizes and specifically binds two antigens or epitopes. The advantages of BsAbs include the potential effects on various cancers, the application to retarget effector cells of the immune system and stimulate them through the interaction to achieve an efficient lysis of tumor cells. On the other hand, BsAbs also have limitations, including low expression of the target structures, non-human nature, limiting the dosage that can be given to patients. For more details, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market” in this document.

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The following pipeline chart summarizes the development status of our selected drug candidates:

Candidate ¹	Target	Technology Platform	Type	Regimen	Indication	Pre-clinical	IND	Phase I Phase IaPhase Ib	Phase II	Phase III/ Pivotal	Commercial Rights	Current Status/ Upcoming Milestone
★ MT01	EpCAMxCD3	YBODY®	BsAb	Mono	Malignant ascites						Global	Phase II commenced in Dec 2021; Expect to initiate Phase III/pivotal trial in Q1 2024 and submit the BLA in Q1 2025
					Malignant pleural effusion						Global	Phase Ib/II commenced in Nov 2022; Expect to initiate Phase III/pivotal trial in Q3 2024 and submit the BLA in Q4 2025
					Solid tumor						Global	Expect to file IND application in Q1 2024 and initiate Phase III/II in Q2 2024
Y101D	PD-L1×TGF-β	Check-BODY	BsAb	Mono	Solid tumors						Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q4 2023
					Pancreatic cancer						Global	Phase Ib/II commenced in Feb 2023; Expect to complete Phase Ib/II in Q3 2024 and initiate Phase III in Q4 2024
					Hepatocellular carcinoma and other advanced solid tumors						Global	Phase Ib/II commenced in Mar 2023; Expect to complete Phase Ib/II in Q2 2025
Y150	CD38×CD3	YBODY®	BsAb	Mono	Small cell lung cancer						Global	Expect to file IND application in Q3 2023; Expect to initiate Phase Ib/II in Q1 2024
					Relapse or refractory multiple myeloma						Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q2 2024
					Relapse or refractory multiple myeloma						Global	Expect to file IND application after the completion of the Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rMM
Y2019³	SARS CoV-2 RBD homodimer	UVAX®	Vaccine	Mono	COVID-19						Global	Completed Phase Ia
N802	HER2×CD3	YBODY®	BsAb	Mono	HER2-positive solid tumors						Global	Completed Phase I
Y332	VEGF×TGF-β	Nano-YBODY™	BsAb	Mono	Solid tumors						Global	IND application approved in Apr 2023; Expect to initiate Phase I in Q3 2023
Y400	VEGF×ANG2	Nano-YBODY™	BsAb	Mono	wAMD, DME and other ocular neovascularization related diseases						Global ⁴ CMS Vision	IND application approved in Apr 2023

★ **Core Product**   **Clinical Stage**  **Pre-clinical Stage**

- Notes:
(1) Except for Y2019, all of our drug candidates are in-house developed.
(2) Specific combination drug(s) of the trial will be decided prior to the commencement of the trial.
(3) We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluates the safety and tolerability of Y2019 in healthy adults, and obtained ethical committee approval for the Phase IIa clinical trial. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.
(4) We have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary for the Phase I and Phase III clinical trials and CMC studies in Phase III clinical trials in China. For more details, please refer to the paragraphs headed "Collaboration Agreements – Collaboration with CMS Vision" in this section.
(5) Some of our drug candidates are not included in the pipeline chart as they are at the early preliminary stage.

Abbreviations: Mono refers to monotherapy; Combo refers combination therapy; EpCAM refers to human epithelial cell adhesion molecule; CD3 refers to cluster of differentiation 3; PD-L1 refers to programmed death ligand 1; TGF-β refers to transforming growth factor-β; CD38 refers to cluster of differentiation 38; COVID-19 refers to coronavirus disease 2019; RBD refers to recombinant receptor-binding domain; HER2 refers to human epidermal growth factor receptor 2; VEGF refers to vascular endothelial growth factor; ANG2 refers to angiopoietin-2; wAMD refers to wet age-related macular degeneration; and DME refers to diabetic macular edema.

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M701 (EpCAM × CD3 BsAb) – Our Core Product

M701 is a recombinant BsAb that targets EpCAM-expressing cancer cells and CD3-expressing T cells. M701 binds to both tumor cells and T cells by using EpCAM as the target on tumor cells and CD3 as the target on T cells, respectively. M701 binds to EpCAM and blocks the downstream signal of EpCAM, and thus can inhibit tumor growth. By binding to T cell surface antigen CD3, M701 promotes T cell activation and proliferation and the release of cytokines to kill tumor cells. M701 also shows cytotoxicity against tumor cells through antibody-dependent cell-mediated cytotoxicity (ADCC), and complement-dependent cytotoxicity (CDC). For more details on the mechanism of action of M701, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Mechanism of Action” in this document.

Clinical development status, results and plan

We completed a Phase I clinical trial of M701 in treating MA in January 2022. We have enrolled a total of 35 subjects in this Phase I trial. Of the 35 enrolled patients, 18 of them have completed the 4-week core treatment period in the escalation phase. Reasons for patients not completing the 4-week core treatment period in the escalation phase primarily include patient withdrawal, and secondarily are disease progression, adverse effects (AEs), and recommendation from the investigators. An objective response rate (ORR) of 61.1% and a disease control rate (DCR) of 94.4% were achieved in this trial. The median overall survival (mOS) reached 151.5 days in this clinical trial. Furthermore, 15 out of 35 enrolled subjects did not experience any TRAE, and only 5 patients experienced Grade 3 TRAEs during the trial, indicating the manageable safety profile of M701. The preliminary claim of efficacy of M701 based on the Phase I data only relies on a limited number of patients and may not be indicative of future clinical results.

We are currently conducting a Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) in MA patients, and expect to complete this clinical trial in the fourth quarter of 2023. After the completion of this Phase II trial, we plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. Furthermore, we are conducting a Phase Ib/II clinical trial of M701 for MPE in China and expect to complete this trial in the third quarter of 2024. Following the completion of this Phase Ib/II trial, we plan to commence a pivotal/Phase III trial for M701 for the treatment of MPE (instead of NSCLC) in China in the third quarter of 2024 and file BLA submission in the fourth quarter of 2025. For more details on the clinical development plan of M701, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Clinical Development Plan” in this document.

Market opportunities

We are developing M701 primarily for the treatment of MA and MPE, which are severe complications that typically occur in late-stage cancer patients who have widespread metastases to the pleura or peritoneum. These patients represent a subset of the overall cancer population. MA commonly occurs in patients with various types of cancer, including ovarian, gastric, and pancreatic cancers. In patients with ovarian cancer, the incidence of MA is about 45%-50%, in gastric cancer patients, the incidence is approximately 25%, and in pancreatic cancer patients, the incidence is around 21%. MPE often occurs in patients with lung cancer, breast cancer, and lymphoma. In lung cancer patients, the incidence of MPE is about 45%, and in breast cancer patients, the incidence is approximately 11%. Considering the incidence rate of MA and MPE in these types of cancer, the incidence of MA and MPE in China reached 591.8 thousand and 605.6 thousand in 2021, is expected to be approximately 654.0 thousand and approximately 683.1 thousand in 2025, respectively, and approximately 729.8 thousand and 779.1 thousand in 2030, respectively. The China market size of MA therapies is expected to grow from RMB10.7 billion in 2021 to RMB12.4 billion in 2025 and RMB14.7 billion in 2030 while China market size for MPE therapies is expected to grow from RMB11.6 billion in 2021 to RMB13.2 billion in 2025 and RMB15.3 billion in 2030. For more details, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM x CD3 Targeted BsAb” in this document.

MA and MPE are serious cancer complications that significantly impact the quality of life of patients. MA can lead to abdominal distension, abdominal pain, bowel obstruction, hypokalemia, hyponatremia, hypoalbuminemia, and anemia, leading to poor appetite, electrolyte disorders, systemic edema, and fatigue. This causes patients to be bedridden and require day care, which increases the cost of care, decreases the quality of life of patients, and

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reduces the opportunity for patients to continue systematic treatments, impacting their survival time. MPE can lead to chest pain, chest tightness, difficulty breathing, accompanied by fatigue, poor appetite, and also reduces the opportunity for patients to receive systematic treatments.

Current treatment options for MA and MPE primarily are medical therapies, including paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration. Given that MA and MPE are complications of cancer, the current treatment paradigm for MA and MPE do not distinguish between first-line/second-line/late-line therapies. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis.

Competitive landscape

As of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins, as illustrated below.

Global Pipeline							
Product	Developer	Highest Clinical Stage	Indication	Region	Drug Type	Target	First Posted Date ⁽¹⁾
Catumaxomab	TRION Pharma GmbH and Neovii Biotech GmbH	Approved in 2009, withdrew from market in 2017, applied for renewal of the marketing authorization in 2022	Cancer, Neoplasms, Carcinoma, MA	France, Germany, Italy, Spain	BsAb	EpCAM, CD3	–
ENDOSTAR™	Jiangsu Simcere Pharmaceutical Co., Ltd.	Phase III	MPE, Malignant Peritoneal Effusion	China	Other Protein	Endostatin	2021/05/27
M701	the Company	Phase II	MA	China	BsAb	EpCAM, CD3	2021/07/23
M701	the Company	Phase Ib/II	MPE	China	BsAb	EpCAM, CD3	2022/08/08
GAIA-102	Gaia BioMedicine Inc; Kyushu University Hospital	Phase II	MA, Stomach Neoplasms, Pancreatic Neoplasms, Carcinoma, NSCLC	Japan	Cell Therapy	–	2021/11/19
RSO-021	RS Oncology LLC	Phase I/II	MPE, Malignant Pleural Mesothelioma, Mesothelioma, Solid Tumor	United Kingdom	Polypeptide	–	2022/02/07
VAK	Wuhan Binhui Biotechnology Co., Ltd.	Phase I	MPE, Malignant Peritoneal Effusion	China	Cell Therapy	–	2022/09/29
IFN-γ and CIK cells, Tem cells or CAR-T cells	Affiliated Hospital of Jiangnan University	Phase I	MPE	China	Cell Therapy	–	2022/03/07

Source: NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

Among them, catumaxomab (developed by TRION Pharma GmbH and Neovii Biotech GmbH) is the world’s first marketed BsAb and has two targets identical to M701 which was approved in 2009 for the treatment of MA. Upon the initial commercial launch of catumaxomab in 2009, based on public information, the medical community’s understanding of immunotherapy and BsAb was not fully developed, which limited the comprehension of the mechanism of actions of catumaxomab, resulting in a relatively cautious approach towards the clinical application of the drug. Moreover, based on public information, the developers of catumaxomab fell short in formulating a market-oriented marketing strategy for catumaxomab, which led to poor sales performance after its launch and its subsequent withdrawal from the

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market in 2017. Catumaxomab was marketed in Europe only and the withdrawal of catumaxomab only impacted the Europe market. The withdrawal of catumaxomab was primarily due to timing and sales strategy instead of safety and efficacy concerns. Despite of that, as the world’s first BsAb drug, the withdrawal of catumaxomab did impact the overall perception of BsAbs within the medical community for a period of time. However, this perception has gradually improved with the increase in marketed BsAb drugs and their clinical use. Catumaxomab demonstrated manageable safety and encouraging efficacy during its clinical use. Therefore, the developers of catumaxomab applied for the renewal of the EMA marketing authorization of the drug for the treatment of MA in August 2022, which is currently under review.

Moreover, peer products targeting identical molecular targets as M701 are under clinical development. According to public information, besides M701, two BsAb pipelines targeting EpCAM, one CD3-targeted mAb, one CD3-targeted antibody fusion protein and one CAR-T pipeline targeting EpCAM are currently under clinical development globally. As of the Latest Practicable Date, these competitors have not developed their EpCAM × CD3 drug candidates for the treatment of MA/MPE, however we cannot guarantee that these companies will not expand into our target market.

For more details of the competitive landscape of M701, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Market Opportunities and Competition – Competitive landscape” in this document.

Limitations and imminent risks on the market potential of M701

We face the following limitations and imminent risks on the market potential of M701:

- MA and MPE, the intended indications of M701, are complications of the tumor. The continual refinement of early tumor detection methods, preventive measures, non-drug treatment options, along with the relentless innovation in tumor treatment methodologies, will reduce tumor prevalence and improve early-stage tumor cure rates, subsequently decreases the occurrence of MA and MPE as complications of the tumor.
- Other therapies for primary and metastatic cancers, including but not limited to chemotherapy, targeted therapies, and immunotherapies, while not directly targeting MA and MPE, can help control these complications. Compared to such systematic treatments that have a curative effect on cancer, M701 is primarily used to improve symptoms and complications of cancer, which might be less attractive to doctors and patients. Approximately 10% of patients with mild symptoms of MA and MPE only need these cancer systematic therapies to control their MA and MPE. These therapies for cancer thereby indirectly limit the market size for M701.
- Current medical treatment methods for MA and MPE, including primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature. Among these current treatment options for MA and MPE, therapeutic paracentesis is recommended by clinical guidelines for controlling MA/MPE which can alleviate symptoms for one to two weeks. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis. However, this method will also be more expensive and may not be affordable by some patients.
- The market size for MA and MPE is relatively limited when compared to the oncology drug market. Comparing with the rapid growth of the oncology drug market in China, the overall growth rate for the China market size of MPE and MA therapies is comparatively stable, which could further limit the market potential of M701.

Y101D (PD-L1 × TGF-β BsAb)

Y101D, a recombinant anti-PD-L1 and anti-TGF-β humanized BsAb, is being developed for the treatment of solid tumors. Y101D is strategically designed to simultaneously inhibit the programmed death 1 (PD-1)/PD-L1 axis and the TGF-β signaling pathways, thus having the potential to unleash a synergistic anti-tumor activity and relieve drug resistance.

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We are currently evaluating Y101D as a monotherapy in a Phase I clinical trial for the treatment of metastatic or locally advanced solid tumors. The interim results of this Phase I clinical study showed an encouraging safety and efficacy profile for Y101D. We commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer in February 2023. We commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of hepatocellular carcinoma (HCC) and other advanced solid tumors in March 2023. In addition, we plan to initiate a Phase Ib/II clinical trial of Y101D in combination with chemotherapy for the treatment of small cell lung cancer (SCLC) in the first quarter of 2024.

The incidence of pancreatic cancer and HCC in China is expected to grow from approximately 115.9 thousand and 388.0 thousand in 2021, respectively, and is expected to increase to approximately 155.8 thousand and 474.2 thousand in 2030, respectively. The addressable late-stage pancreatic cancer and HCC patients of Y101D is estimated to reach 104.7 thousand and 222.9 thousand, respectively, in China in 2030. For more details about the addressable markets of late-stage pancreatic cancer and HCC therapies, please refer to the paragraphs headed “Industry Overview – PD-1/PD-L1 × TGF-β Targeted Drugs Market – China’s Market of PD-1/PD-L1 × TGF-β Targeted Drugs” in this document.

No PD-1/PD-L1 × TGF-β BsAb drug is marketed either globally or in China. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody receptor fusion proteins, according to the CDE and the ClinicalTrials.gov websites. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis between BsAb and fusion protein antibodies, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

For more details of Y101D, please refer to the paragraphs headed “Business – Our Drug Candidates – Y101D (PD-L1 × TGF-β BsAb)” in this document.

Y150 (CD38 × CD3 BsAb)

Y150 is a recombinant anti-CD38 and anti-CD3 humanized BsAb consisting of a fully human anti-CD38 Fab-Fc moiety and a humanized anti-CD3 scFv-Fc moiety. Y150 is well-designed to bind to both CD38 on multiple myeloma (MM) tumor cells and CD3 on T cells, inducing the activation of the T cells, improving the targeting of activated T cells, and allowing the activated T cells to attack the target tumor cells.

We are developing Y150 for the treatment of relapse or refractory multiple myeloma (rrMM) in a Phase I clinical trial. The incidence of MM is expected to increase from approximately 21.7 thousand in 2021 to 27.7 thousand in 2030, and the addressable rrMM patients of Y150 is estimated to reach 60.4 thousand in 2030 in China. For more details about the addressable market of rrMM therapies, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – CD38 × CD3 Targeted BsAbs – Multiple Myeloma (MM)” in this document. Current treatment regimens can prolong patient survival only and patients will eventually relapse and succumb to their disease. For most of the patients, MM will eventually develop into rrMM. This makes patients require continuous treatment in order to manage MM as a chronic disease and prefer treatment regimens with convenient administration. Therefore, there remains a need for patients whose disease has relapsed after, or is refractory to, available MM therapies. According to the CDE and the ClinicalTrials.gov websites, there is no CD38 targeted BsAb approved for marketing globally, and Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into the clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. Outside of China, there is only one CD38 × CD3 BsAb, namely ISB-1342 of Ichnos Sciences, under development in a Phase I clinical trial. Besides that, SAR442257, an anti-CD38/CD28/CD3 antibody being developed by Sanofi, is also under clinical development, evidencing the therapeutic potentials of the CD38 and CD3 targets. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis of BsAb and fusion protein antibodies, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

We are currently evaluating Y150 in a Phase I clinical trial in rrMM in China. The interim results of the Phase I clinical study for Y150 in rrMM in China showed an encouraging safety profile for Y150. We will further explore the clinical efficacy of Y150 monotherapy in treating rrMM patients as well as its potentials in combination therapy. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We also plan to

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initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM. For more details of Y150, please refer to the paragraphs headed “Business – Our Drug Candidates – Y150 (CD38 × CD3 BsAb)” in this document.

Y2019 (RBD-dimer Subunit SARS-CoV-2 Vaccine)

Y2019 is a recombinant RBD-dimer subunit SARS-CoV-2 vaccine candidate for COVID-19. We have taken a collaborative approach to develop Y2019.

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluated the safety and tolerability of Y2019 in healthy adults aged 18 years or older, and have obtained satisfactory 7-day and 90-day safety data post immunization. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

M802 (HER2 × CD3 BsAb)

M802 is an anti-human epidermal growth factor receptor 2 (HER2) and anti-CD3 humanized BsAb consisting of a monovalent unit that specifically binds to HER2 and a single chain unit that binds to CD3.

We are developing M802 for the treatment of HER2-positive solid tumors. HER2 is highly expressive in many types of cancers, including breast cancer, gastric cancer and ovarian cancer. The addressable late-stage HER2-positive gastric cancer and late-stage HER2-positive breast cancer patients of M802 is estimated to reach 39.4 thousand and 13.6 thousand, respectively, in China in 2030. For more details about the addressable market of HER2-positive cancer therapies, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – HER2 × CD3 Targeted BsAb – Market of HER2 Targeted BsAb” in this document. As of the Latest Practicable Date, there were ten HER2-targeted BsAb pipelines under clinical development globally (excluding China), and 13 HER2-targeted BsAb pipelines in China. The development of HER2 × CD3 BsAbs represents an emerging trend. As of the Latest Practicable Date, there were four HER2 × CD3 BsAbs under clinical development globally, including M802, RG6194, EX 101 Injection and AMX 818.

We have completed a Phase I clinical trial for M802 in China. Data obtained from the Phase I clinical trial of M802 also indicates that M802 has a favorable safety profile. We will consider exploring potential out-licensing opportunities of M802 in the global market. For more details of M802, please refer to the paragraphs headed “Business – Our Drug Candidates – M802 (HER2 × CD3 BsAb)” in this document.

Y332 (VEGF × TGF-β BsAb)

Y332, a recombinant anti-vascular endothelial growth factor (VEGF) and anti-TGF-β BsAb, is being developed for the treatment of a variety of solid tumors. In pre-clinical studies, Y332 showed high affinity to both VEGF and TGF-β, and demonstrated encouraging anti-tumor effects. Y332 can also be used in combination with immune checkpoint inhibitors to deliver an enhanced anti-tumor effect. According to the CDE website, there is currently only one VEGF × TGF-β BsAb, namely ZGGS18, that has entered into clinical development in China. We are conducting chemistry, manufacturing, and controls (CMC) studies for Y332 and have filed an IND application with the NMPA in January 2023. We received IND approval for Y332 in April 2023. For more details of Y332, please refer to the paragraphs headed “Business – Our Drug Candidates – Y332 (VEGF × TGF-β BsAb)” in this document.

Y400 (VEGF × ANG2 BsAb)

Y400 is a recombinant anti-vascular endothelial growth factor (VEGF) and anti-angiopoietin-2 (ANG2) BsAb for the treatment of wAMD and DME. The addressable wAMD and DME patients of Y400 is estimated to reach 3.4 million and 2.7 million, respectively, in 2030 in China. For more details about the addressable markets of wAMD and DME therapies, please refer to the paragraphs headed “Industry Overview – VEGF × ANG2 Targeted Bispecific Antibody Market – China’s Market of wAMD and DME Treatment” in this document. The CMC studies for Y400 have been completed and the CDE approved the IND application for Y400 in April 2023. As a testament to our strong R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, as well as tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. For more details of Y400, please refer to the paragraphs headed “Business – Our Drug Candidates – Y400 (VEGF × ANG2 BsAb)” in this document.

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Our Research and Development

We have built an integrated research and development platform that encompasses three main functions: drug discovery and pre-clinical development function, CMC function and clinical development function. With collaboration among such functional groups, we are able to bring our strong pipeline from inception through development, manufacturing and commercialization. As of the Latest Practicable Date, our research and development team consisted of 99 employees, 46.5% of which have a master’s degree or higher. Our research and development team members have extensive pre-clinical and clinical development experience, focusing on oncology and immunology. Our key R&D staff have an average of 12 years of relevant experience working in the biopharmaceutical industry. In 2021 and 2022, our total research and development expenses were RMB112.9 million and RMB157.3 million, respectively, and the research and development expenses attributable to our Core Product, M701, amounted to RMB9.9 million and RMB23.5 million, representing approximately 8.7% and 15.0% of the total research and development expenses for the same years, respectively. In 2021 and 2022, our total research and development expenses accounted for approximately 78.2% and 88.5% of our operating expenses (being the research and development expenses and administrative expenses) for the same years, respectively. For details about our research and development capability, please refer to the paragraphs headed “Business – Our R&D Platform” in this document.

Our Platforms

Equipped with our platform technologies, we stand at the forefront in discovering and developing drug candidates for the treatment of cancer and age-related ophthalmologic diseases. We have strategically developed four innovative platforms, including the self-developed YBODY[®] platform, Check-BODY platform and Nano-YBODY[™] platform, and UVAX[™] platform developed in collaboration with WIV.

- Our YBODY[®] platform is a BsAb platform that focuses on the development of asymmetric human immunoglobulin G (IgG)-like BsAbs with the structure of single-chain variable fragment – antigen-binding fragment – crystallizable fragment (scFv-Fab-Fc structure). The BsAbs with scFv-Fab-Fc structure developed by the YBODY[®] platform have unique features, including (i) favorable safety profile with low cytokine release syndrome-related toxicity due to their reduced affinity with human immune cells, (ii) high drug product purity of 99%, (iii) minimized mispairing between the heavy chains and light chains of BsAbs, (iv) favorable pharmacokinetics (PK) and pharmacodynamics (PD) profile, and (v) high stability. We can achieve 99% product purity of the YBODY[®] molecules by (a) achieving over 90% accurate pairing of heavy chains based on the technologies of the YBODY[®] platform and (b) eliminating those less than 10% mismatches in heavy chains by applying the traditional protein purification process techniques. Based on YBODY[®] platform, we have developed three T cell-engaging BsAbs, namely M701, M802 and Y150.
- Our Check-BODY platform is designed to develop symmetric tetravalent BsAbs. Both Fab and Fv fragments of a Check-BODY molecule show high affinity to the targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like monoclonal antibodies (mAbs) and therefore is easier to achieve. We are able to develop Check-BODY molecules with consistent high quality in multiple batches, and can easily scale up the production of Check-BODY molecules. We have discovered and developed Y101D, an anti-programmed death ligand 1 (PD-L1) and anti-transforming growth factor β (TGF- β) BsAb, based on the technologies of our Check-BODY platform.
- Our Nano-YBODY[™] platform is designed to develop symmetric tetravalent BsAbs based on single-domain antibodies. The well-designed structure enables Nano-YBODY[™] molecules to achieve higher binding affinity, better stability, lower immunogenicity and higher production yield than other BsAbs. We have discovered and developed Y400 and Y332 based on the technologies of Nano-YBODY[™] platform. As a testament to our strong R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with CMS Vision” in this document. We have received the full upfront payment of US\$5 million for Y400.

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- Our UVAX[®] platform is a unique immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our proprietary BsAb engineering technologies. We utilize our UVAX[®] platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield Chinese hamster ovary (CHO) expression and antibody-like purification systems. We have discovered and developed Y2019, based on the technologies of the UVAX[®] platform.

These platforms serve as an engine for our continuous endeavor to deliver new drug candidates, including potential drug candidates we may develop in the future utilizing the molecular structures and CMC processes of the platforms. To protect our proprietary technologies and maintain our competitive advantages, we have built a comprehensive patent portfolio for our platforms. Leveraging our platform technologies, we are able to design and generate different antibody structures, and therefore can quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways.

For more details, please refer to the paragraphs headed “Business – Our R&D Platform – Drug Discovery and Pre-clinical Development – Our Proprietary Technology Platforms” in this document.

Our Business Model

Our core business model is to in-house discover, develop and commercialize BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. All of our drug candidates and platform technologies are in-house developed, except for Y2019 and UVAX[®] platform which we develop in collaboration with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV).

We have been dedicated to developing BsAb-based therapies since our inception in 2010. As of the Latest Practicable Date, five of our seven pipeline drug candidates were BsAbs designed for the treatment of some of the most significant cancer types as well as cancer-associated complications such as MA and MPE. In particular, we have been focusing on the development of the T cell-engaging BsAbs, including M701, M802 and Y150, and the development of the tumor microenvironment (TME)-targeted BsAbs, including Y101D and Y332. During the Track Record Period, we have invested a significant portion of our efforts and financial resources in the development of BsAbs designed for cancer treatment. In 2021 and 2022, the R&D expenses attributable to the five BsAbs for the treatment of cancer and its complications in our pipeline amounted to RMB58.2 million and RMB80.4 million, respectively. For details about our key development milestones for BsAbs for cancer treatment, please refer to the paragraphs headed “History, Development and Corporate Structure – Milestones” in this document.

Our ability to design and develop BsAbs is largely driven by our solid core technology platforms, namely YBODY[®], Check-BODY and Nano-YBODY[™]. M701, Y150 and M802 were designed and generated by YBODY[®], Y101D was designed and generated by Check-BODY, while Y332 and Y400 were generated by Nano-YBODY[™]. Leveraging our advanced platform technologies, we are able to design and generate different antibody structures. For more details about our R&D capability and technology platforms, please refer to the paragraphs headed “Business – Our R&D Platform” in this document.

We are committed to the continuous development and commercialization of BsAb-based therapies. We will continue to advance the development of our drug candidates for cancer treatment and invest more resources in the clinical development and pre-clinical studies of these drug candidates. Particularly, we plan to use a significant portion of our [REDACTED] from the [REDACTED] for ongoing and planned clinical trials, preparation for registration filings, and planned commercial launch (including sales and marketing activities) of drug candidates for treatment of cancer and its complications. For more details, please refer to the section headed “Future Plans and [REDACTED]” in this document.

To complement our internal efforts, we have entered into collaboration arrangements with third parties in relation to the development of certain of our drug candidates. For details, please refer to the paragraphs headed “– Collaboration Agreements” in this section. In the future, we will continue to seek strategic collaborations with resourceful partners and form additional strategic alliances or other collaborations, and we currently do not intend to out-license or seek collaboration with third parties in relation to our Core Product.

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We face pricing pressure for our BsAb drug candidates due to fierce competition in the market. Current medical treatment methods for MA and MPE, primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature. To maximize the market potential of M701 after its commercialization, we will adopt a more flexible pricing strategy for M701 with an aim to provide affordable drugs to patients and to benefit the patients. We will take into consideration clinical demands by MA and MPE patients, clinical value of M701, our market share, the competitive landscape and the price level of other available treatment options for MA or MPE in the relevant market. Furthermore, we may also face pricing pressure for our BsAb drug candidates to be included in the National Reimbursement Drug List (NRDL) in China due to their high costs of development and manufacturing. In China, prices of pharmaceutical products are currently determined mainly by market competition. 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. In addition, we may face competition from international and Chinese biopharmaceutical conglomerates who may operate on lower margins based on their economies of scale.

To navigate through such pricing pressure and competition, we (i) develop our Core Product, M701, with differentiated market positioning for the treatment of MA and MPE, (ii) develop stable, high-yield processes under our proprietary technology platforms, including YBODY®, Check-BODY and Nano-YBODY™, to produce high-purity BsAb, (iii) maintain clinical dosages of our drug candidates at the microgram or milligram level with our high-yield CMC process, ensuring that each treatment course requires minimal medication quantities, thus lowering costs of treatment of our drug candidates and balancing patient affordability with our profitability, and (iv) seek strategic collaborations and contract part of our manufacturing process to CMOs/CDMOs to reduce upfront investment costs.

For more details about our business model, please refer to the paragraphs headed “Business – Overview – Our Business Model” in this document.

OUR STRENGTHS

We believe the following competitive strengths have contributed to our success and differentiate us from our competitors:

- A pioneer standing at the forefront of the development of BsAbs in China;
- Advanced technology platforms fueling the research and development of drug candidates;
- A strong pipeline of drug candidates with market potential leveraging our differentiated clinical development strategies;
- A robust and GMP-compliant CMC platform; and
- Visionary, seasoned and execution-driven management and R&D teams with a proven track record.

For more details, please refer to the paragraphs headed “Business – Our Strengths” in this document.

OUR STRATEGIES

We intend to pursue the following strategies to further our business growth.

- Accelerate the development of our drug candidates;
- Continue to expand our pipeline through in-house R&D efforts and collaborations;
- Continue to enhance our manufacturing capabilities;
- Continue to build our commercialization capabilities; and
- Continue to attract, nurture and retain skilled talent.

For more details, please refer to the paragraphs headed “Business – Our Strategies” in this document.

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OUR MAJOR SUPPLIERS

During the Track Record Period, our purchases mainly included third-party contracting services for preclinical evaluation and clinical trials of our drug candidates, raw materials, consumables, machines, and equipment. Our major suppliers primarily consist of CROs, CDMOs, CMOs, and suppliers of equipment, devices, and consumable items located in China.

For the years ended December 31, 2022 and 2021, the aggregate purchases attributable to our five largest suppliers in each year were RMB68.0 million and RMB24.5 million, respectively, representing 48.4% and 37.7% of our total purchases for the same years, respectively. Purchases attributable to our single largest supplier in each year were RMB50.0 million and RMB9.0 million, accounting for 35.3% and 13.8% of our total purchases for the same years, respectively. We believe that we maintain strong and stable relationships with our major suppliers.

COLLABORATION AGREEMENTS

Collaboration with CMS Vision

On July 26, 2022 (the “Effective Date”), we entered into an asset transfer agreement (the “CMS Agreement”) with Shenzhen Kangzhe Vision Pharmaceutical Development Co., Ltd. (深圳市康哲維盛醫藥發展有限責任公司) (formerly known as Kangzhe Pharmaceutical Research and Development (Shenzhen) Limited (深圳康哲醫藥發展有限公司)) (“CMS Vision”), a wholly-owned subsidiary of China Medical System Holdings Limited (0867.HK) (together with its subsidiaries, the “CMS Group”), to transfer all of the rights and assets relating to Y400 to CMS Vision.

The parties shall establish a joint steering committee (“JSC”) with an equal number of representatives from each party. All decisions of the JSC shall be made by unanimous vote with each party’s representatives collectively having one vote. In case of any disagreement that cannot be resolved by negotiations, CMS Vision shall have the final decision-making authority over all matters relating to the development, manufacturing and commercialization of Y400 in the Territory (as defined below).

Pursuant to the CMS Agreement, we agree to, subject to certain special arrangement with respect to the United States, Europe and Japan, transfer all of the rights and assets relating to Y400 for any indication worldwide (the “Territory”) to CMS Vision, including but not limited to: (i) all of the rights, proprietary technologies, regulatory approvals and assets (tangible and intangible) that are necessary to use, develop, register, make, have made, sell, distribute, promote and commercialize Y400; (ii) all of the intellectual property rights (including trademarks, patents, know-how and applications thereof) relating to Y400; and (iii) all of the cell bank, data, materials, information, filings and records relating to Y400, as well as all of the rights obtained or otherwise generated from all the pre-clinical and clinical studies and experiments conducted for the purpose of applying and receiving regulatory approvals and intellectual property rights for Y400, that are currently owned or controlled by, or will be owned or controlled by, us and our affiliates. We also agree to grant a non-exclusive sublicense to CMS Vision with respect to an upstream cell line which we have sublicensed from a third party relating to Y400.

We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (a) the IND application and (b) the Phase I clinical trial, if any, in accordance with the standards and requirements by the CDE. CMS Vision, at its own cost, is responsible for the IND applications, clinical development, regulatory activities and commercialization of Y400 in the Territory, and we provide all necessary support and assistance. CMS Vision is entitled to manufacture Y400 for clinical use, use in regulatory approval or in commercial sales by itself or engage us/a CMO.

We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, as well as tiered royalties based on net sales. We have received the full upfront payment of US\$5 million from CMS Vision.

For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with CMS Vision” in this document.

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Collaboration with WIV

In July 2020, we entered into an agreement with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV), for our collaboration in the research and development of Y2019.

Pursuant to our agreement with WIV, we are responsible for leading the clinical trials of Y2019 and the filing of IND and NDA submissions under the names of both parties. Upon mutual agreement by the parties, WIV will conduct the antibody activity assay and animal studies during the clinical development of Y2019, and we will provide reimbursements for such activities.

Pursuant to our agreement with WIV, we and WIV shall jointly own intellectual property rights of Y2019 arising from our collaboration. Upon the commercialization of Y2019, WIV is entitled to 4% of annual sales revenue.

For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with WIV” in this document.

COLLABORATION WITH CROS, SMOS, CMOS/CDMOS, AND OTHER THIRD PARTIES

In line with the practice in the pharmaceutical industry, we use CROs, SMOs, CMOs/CDMOs, and third-party research centers to conduct and support our preclinical studies and clinical trials. We closely supervise the activities of these third party collaborators. We have selected these institutions weighing various factors, such as their qualifications, expertise, experience, reputation and costs.

For more details, please refer to the paragraphs headed “Business – Our R&D Platform – Clinical Development – Collaboration with CROs, SMOs, CMOs/CDMOs and Other Third Parties” in this document.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we owned (i) 21 issued patents in the PRC, (ii) eight issued patents in the United States, (iii) four issued patents in other jurisdictions, and (iv) 45 patent applications, including 15 pending PRC patent applications, five pending U.S. patent applications, five pending PCT patent applications which have not entered into national phases, and 20 pending applications in other jurisdictions. As of the Latest Practicable Date, we self-owned all of our material patents as well as patent applications. We owned two PCT applications in relation to M701, including one PCT application that is generally applicable to our YBODY[®] molecules, including M701 and M802, and one PCT application specifically relating to M701. One PCT application had entered into national phase in major markets, including five granted patents in China, Canada, the U.S. and Japan, and one pending patent applications in China; and the other PCT application was published. For more details, please refer to the paragraphs headed “Business – Intellectual Property” in this document.

DATA PRIVACY AND PROTECTION

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards. We have established procedures to protect the confidentiality of patients’ data. We also require external parties and internal employees involved in clinical trials to comply with confidentiality requirements.

For more details, please refer to the paragraphs headed “Business – Data Privacy and Protection” in this document.

SUMMARY OF HISTORICAL FINANCIAL INFORMATION

The following tables set forth summary financial data from our consolidated financial information for the Track Record Period, extracted from the Accountants’ Report set out in Appendix I to this document. The summary consolidated financial data set forth below should be read together with, and is qualified in its entirety by reference to, the consolidated financial statements in this document, including the related notes. Our consolidated financial information was prepared in accordance with the International Financial Reporting Standards (“IFRSs”).

SUMMARY

Summary of Consolidated Statements of Profit or Loss and Other Comprehensive Expenses

The table below sets out our consolidated statements of profit or loss and other comprehensive expenses for the years indicated derived from the Accountants’ Report included in Appendix I to this document.

	Year ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Other income	12,798	2,560
Other gains and losses	716	671
Research and development expenses	(112,893)	(157,329)
Administrative expenses	(31,497)	(20,525)
[REDACTED] expenses	[REDACTED]	[REDACTED]
Finance costs	(14,972)	(2,468)
Loss before tax	(148,518)	(188,866)
Loss and total comprehensive expenses for the year	(148,518)	(188,866)

Our loss and total comprehensive expenses increased from RMB148.5 million in 2021, to RMB188.9 million in 2022, mainly due to the increase of our research and development expenses.

Our research and development expenses increased from RMB112.9 million for the year ended December 31, 2021 to RMB157.3 million for the year ended December 31, 2022. The increase was primarily due to (i) the expenses incurred from the technical service for Phase I clinical trials of Y150, Y101D and Y2019, and the Phase II clinical trial of M701; (ii) the increase in our purchases of raw materials as a result of increased production of stock solutions and reagents for Y332 and Y400; and (iii) the increased cost of Y332 and Y400 in relation to their pharmacodynamic research and preclinical safety evaluation. Such increase was partially offset by the decrease in employee benefits expenses as we did not grant share-based payments for research and development employees in 2022.

For more details, please refer to the paragraphs headed “Financial Information – Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Expenses” and “Financial Information – Period to Period Comparison of Results of Operations” in this document.

Summary of Consolidated Statements of Financial Position

The table below sets out selected information from our consolidated statements of financial position as of the dates indicated, which has been extracted from the Accountants’ Report included in Appendix I to this document.

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Total non-current assets	74,517	63,885
Total current assets	125,638	238,957
Total assets	200,155	302,842
Total current liabilities	56,908	146,960
Net current assets	68,730	91,997
Total non-current liabilities	83	–
Total liabilities	56,991	146,960
Net assets	143,164	155,882

SUMMARY

Our net current assets increased from RMB68.7 million as of December 31, 2021 to RMB92.0 million as of December 31, 2022, primarily due to the combined effects of (i) an increase in cash and cash equivalents as a result of the completion of the Series C Financing in October 2022; (ii) an increase in financial assets at FVTPL reflecting our investment in certain structured deposits and wealth management; (iii) an increase in bank borrowings; and (iv) an increase in advance from the CMS Agreement as a result of the fixed upfront fee, which will be required to refund upon certain conditions.

Our net assets increased from RMB143.2 million as of December 31, 2021 to RMB155.9 million as of December 31, 2022, mainly due to the combined effects of (i) an increase in share capital of RMB14.0 million and an increase of share premium of RMB186.0 million, as our Company issued 14,000,000 ordinary shares at the consideration of RMB200.0 million to investors in October 2022, (ii) an increase in equity-settled share-based payments of RMB1.6 million recognized for the same period, and (iii) an increase in loss and total comprehensive expense of RMB188.9 million in 2022.

For more details, please refer to the paragraphs headed “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position” in this document.

Summary of Consolidated Statement of Cash Flows

The following table sets forth a summary of our cash flows for the years indicated.

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Net cash used in operating activities	(98,710)	(176,703)
Net cash (used in) from investing activities	(19,933)	5,804
Net cash from financing activities	81,034	241,334
Net (decrease) increase in cash and cash equivalents	(37,609)	70,435
Cash and cash equivalents at beginning of the year	120,694	83,085
Cash and cash equivalents at the end of the year	83,085	153,520

During the Track Record Period, we incurred net operating cash outflows primarily in relation to our research and development expenses, and administrative expenses. For more details, please refer to the paragraphs headed “Financial Information – Liquidity and Capital Resources – Cash Flows – Operating Activities.”

Our Directors are of the opinion that, taking into account the financial resources available, including cash and bank balances and the estimated [REDACTED] from the [REDACTED], as well as our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, general and administrative expenses and other operating expenses for at least the next 12 months from the date of this document.

SUMMARY

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including clinical development and business development activities; (ii) purchase of property and equipment; (iii) interest paid; (iv) interest paid on lease liabilities; and (iv) payments of lease liabilities. We had cash and cash equivalents of RMB104.7 million as of April 30, 2023. Assuming an average cash burn rate going forward of 1.0 times of the level in 2022, we estimate that our cash and cash equivalents and financial assets at fair value through profit or loss as of April 30, 2023 will be able to maintain our financial viability for 16 months taking into account the estimated [REDACTED] from the [REDACTED] (based on the low-end of the indicative [REDACTED] range stated in this document). Our Directors and management team will continue to monitor our working capital, cash flows, and our business development progress. We monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months. In the event our business operations experience any material and adverse impact, we will proactively manage our cash flows and control our costs and expenses; on the other hand, in the event we identify any additional promising research and development projects, or identify any suitable target for investment or acquisition, we may adjust our financing plans to take advantage of such opportunities. We may also diversify our source of funding to further support the development of our product candidates going forward.

Key Financial Ratios

The following table sets forth certain of our key financial ratios for the years indicated.

	As of December 31,	
	2021	2022
Current ratio ⁽¹⁾	2.2	1.6

(1) Current ratio is calculated by current assets divided by current liabilities as of the same date.

For more details, please refer to the paragraphs headed “Financial Information – Key Financial Ratios” in this document.

OUR SINGLE LARGEST SHAREHOLDER GROUP

Pursuant to a concert party agreement dated June 30, 2018, and supplemental concert party agreements dated October 26, 2020 and June 2, 2023 entered into by Yuan Qian, Dr. Zhou Hongfeng, Dr. Zhou Pengfei and Wuhan Caizhi (each an “AIC Party”, collectively, “AIC Parties”), the AIC Parties agreed (i) to act in concert by way of reaching consensus on proposals related to the Group’s daily management and operation presented to all general meetings and Board meetings of the Company; and (ii) that when no consensus can be reached, the AIC Parties shall vote in concurrence with Yuan Qian on the proposals, or, in the event of Yuan Qian’s absence from voting, the AIC Parties shall vote in concurrence with the AIC Party with the highest shareholding percentage among the AIC Parties who votes at the meetings. As of the Latest Practicable Date, the AIC Parties, being our single largest shareholder group, were in aggregate entitled to exercise approximately 29.81% (slightly lower than 30%) of the voting rights in our Company, which have only been diluted upon the completion of the Series C Financing in October 2022 prior to our submission of the [REDACTED] form to the Stock Exchange. Upon completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), the AIC Parties will hold approximately [REDACTED]% of our total issued share capital. For more details, please refer to the paragraphs headed “History, Development and Corporate Structure – Concert Party Arrangement” in this document.

SUMMARY

[REDACTED] INVESTMENTS

We have attracted certain investors to raise funds for the development of our business. As of the Latest Practicable Date, we have completed six rounds of [REDACTED] investments, including: (i) Series Pre-A Financing; (ii) Series A Financing; (iii) Series B Financing; (iv) Series B+ Financing; (v) Series B++ Financing; and (vi) Series C Financing. The equity interests held by Series Pre-A Financing investors were all subsequently transferred to other Shareholders. Our Group raised a total of approximately RMB712.2 million through the [REDACTED] investments (including the Additional Consideration (as defined in “History, Development and Corporate Structure”). Our [REDACTED] Investors include Sophisticated Investors, such as CSPC-NBP, who has made meaningful investment in the Company at least six months before the [REDACTED] and will hold approximately [REDACTED]% of the total issued share capital of the Company upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised). For more details of the identity and background of the [REDACTED] Investors, please refer to the section headed “History, Development and Corporate Structure” in this document.

DIVIDEND

We did not declare or pay any dividend during the Track Record Period. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, as determined in accordance with its articles of association and the accounting standards and regulations in China. As a result, we may not have sufficient or any distributable profits to make dividend contributions to our Shareholders, even if we become profitable.

USE OF [REDACTED]

We estimate that the aggregate [REDACTED] to our Company from the [REDACTED] (after deducting [REDACTED] and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any additional discretionary [REDACTED] and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) will be approximately HK\$[REDACTED].

We intend to use the [REDACTED] as follows (based on the mid-point of the [REDACTED] range stated in this document):

- (i) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials, preparation for registration filings, and planned commercial launch (including sales and marketing activities) of M701, our Core Product;
- (ii) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials of Y101D; and
- (iii) approximately [REDACTED]%, or HK\$[REDACTED], will be used for working capital and general corporate purposes.

For more details, please refer to the section headed “Future Plans and Use of [REDACTED]” in this document.

SUMMARY

RISK FACTORS

Investing in the [REDACTED] involves certain risks as set out in the section headed “Risk Factors” in this document. Some of the major risks we are exposed to are as follows:

- Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed;
- We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do. For instance, our Core Product, M701, faces competition from current medical treatment methods for MA and MPE which are less costly in nature, and competition from multiple peer products under development for the treatment of MA and MPE and peer products targeting identical molecular targets as M701. Furthermore, we face indirect competition from other therapies for primary and metastatic cancers that do not directly target MA and MPE but can help control these complications;
- The development of BsAbs is a nascent field and faces many imminent risks and challenges. The development of BsAbs involved more difficulties and risks due to the complex molecular design and mechanisms of action, and typically incur higher production costs. BsAbs cannot be administered orally, thus the less convenient administration methods of BsAbs increase treatment costs and safety risks associated with infusions. BsAbs face intense competition from mAbs, antibody-drug conjugates, multi-specific antibodies and fusion protein antibodies, which may surpass BsAbs in terms of cost, R&D difficulty, success rate and market acceptance;
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis;
- 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;
- All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with existing or future regulations and industry standards or any adverse actions by drug approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects;
- We have limited experience in the commercialization of drugs. If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue; and
- We have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

For more details, please refer to the section headed “Risk Factors” in this document.

SUMMARY

[REDACTED]

[REDACTED] EXPENSES

[REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (including [REDACTED]), based on the mid-point of our indicative [REDACTED] for the [REDACTED]), assuming no Shares are [REDACTED] pursuant to the [REDACTED]. During the Track Record Period, we incurred [REDACTED] expenses of approximately RMB [REDACTED], among which RMB[REDACTED] was recognized in our consolidated statements of profit or loss and other comprehensive income, and approximately RMB[REDACTED] ([REDACTED] expenses directly attributable to the [REDACTED] of Shares) will be deducted from equity upon [REDACTED]. After December 31, 2022, approximately RMB[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] is expected to be charged against equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

The [REDACTED] expenses are expected to represent approximately [REDACTED]% of the [REDACTED] of the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED] range) and that the [REDACTED] is not exercised. The [REDACTED] expenses are comprised of: (i) [REDACTED] expenses of RMB[REDACTED]; and (ii) [REDACTED] expenses of [REDACTED], which can be further broken down into: (A) fees and expenses of legal advisors and accountants of RMB[REDACTED]; and (B) other fees and expenses of RMB[REDACTED].

SUMMARY

RECENT DEVELOPMENT

In January 2023, the IND applications were successfully filed with the NMPA for Y332 and Y400.

In February 2023, we commenced the Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer.

In April 2023, we received the IND approval for Y332 for metastatic or locally advanced solid tumors and the CDE approved the IND application for Y400.

We expect an increase in forecast loss in the year ended December 31, 2023, primarily because we expect to incur increasing R&D expenses and administrative expenses as we continue to carry out and expand our clinical development programs and advance the research and development of pre-clinical assets.

IMPACT OF THE COVID-19 OUTBREAK

Since late 2019, COVID-19 has spread rapidly globally. Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 cases in several parts of China due to the spread of the Omicron variant. We have employed various measures to mitigate any impact the COVID-19 pandemic may have on our operations, including offering personal protection equipment such as masks to our employees, regularly checking the body temperature of our employees and closely monitoring their health conditions.

The COVID-19 outbreak and resurgences in China and the quarantine measures taken by the PRC government had only limited impact on us. From early 2020 to December 2022, we experienced increased difficulties in patient enrollment for the Phase I and Phase II clinical trials of M701 for the treatment of MA. Specifically, for the Phase II clinical trial of M701 for the treatment of MA, we originally planned to have the first patient in October 2021 and expected to enroll eight to ten patients per month. However, due to the lockdown measures implemented by local governments where our research institutions are located, we did not have our first patient in until December 2021 and the number of patients enrolled in the Phase II clinical trial of M701 for the treatment of MA was approximately six per month from December 2021 to April 2022, lower than what we originally expected. The above disruptions in combined, lead to certain delays in advancing the clinical development of M701 and relatively lower R&D expenses for M701 during the Track Record Period. We also experienced temporary delays in subject enrollment for our clinical trials in certain regions, such as Beijing, Shanghai and Henan province, for one to three months in 2022. Nevertheless, we resumed the normal patient enrollment for these clinical trials later, and the resurgences and quarantine measures did not cause any material impact on our clinical trials, including any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We employed various measures to mitigate any impact the COVID-19 outbreak and resurgences may have on our ongoing clinical trials in China, including providing alternative methods for safety and efficacy assessment, continuing patient visit through remote access, and engaging necessary communications with our investigators to identify and address any issues that may arise. The expected development progress of our drug candidates has taken into account the temporary delays and disruptions on our ongoing clinical trials caused by the COVID-19 resurgences. With regard to the impact of the resurgence of COVID-19 outbreak since December 2022, most of our employees were infected with the COVID-19, and then recovered within a short period of time. Our operations for clinical trials experienced disruptions, however, such delays were temporary and we resumed the normal patient enrollment since January 2023. For example, the number of patients we enrolled for all of our ongoing clinical trials increased from eight in January 2023 to eleven in February 2023, and further to 16 patients in March 2023, among which we enrolled three, seven and ten patients for clinical trials of M701 in January, February and March 2023, respectively. In addition, as such resurgence was less severe because of lower mortality rate and higher curability rate than that of the initial COVID-19 outbreak in early 2020, and taking into account that the COVID-19 related governmental measures have been gradually lifted in China (such as the government’s releasing measures to lift up quarantine measures and travel restrictions to accelerate the economic recovery and resume normal operations of the society), our Directors were not aware of any material adverse impact of such resurgence on our operations and financial performance.

SUMMARY

Although the COVID-19 related restrictive measures adopted by the Chinese government has been lifted in various regions in China since December 2022, it is still uncertain whether the continuance or future recurrence of the COVID-19 outbreak in China will have a material adverse effect on our business, results of operations, financial position or prospects. The recent COVID-19 outbreaks in China, and future resurgences, if any, may adversely affect our operations if any of our employees or employees of our suppliers and other business partners are suspected of contracting or contracted COVID-19, as we, our suppliers or our business partners may arrange such employees to work remotely at home or disinfect the operating facilities. The ongoing clinical trials and the commencement of new clinical trials for our drug candidates could also be delayed if, due to the COVID-19 outbreak and resurgences in China, there is any delay or failure in subject recruitment or enrollment and/or any diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials from the conduct of clinical trials.

In view of the above situation, our Directors confirm that the COVID-19 outbreak did not have a material adverse impact on our business operations and financial performance as of the Latest Practicable Date, as (i) there had been no material disruption of our ongoing clinical trials or research and development efforts; and (ii) we had not encountered any material supply chain disruption and had not experienced any material difficulties in procuring major raw materials.

The extent to which the COVID-19 outbreak impacts on 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. We cannot foresee whether COVID-19 will have a material and adverse impact on our business going forward. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We face risks related to health epidemics and other outbreaks of contagious diseases, including the COVID-19 outbreak” in this document. We will closely monitor and evaluate any impact of the COVID-19 outbreak and resurgences on us and adjust our precautionary measures according to its developments.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, as of the date of this document, there has been no material adverse change in our financial or trading position, indebtedness, contingent liabilities or prospects of our Group since December 31, 2022, the end of the period reported on in the Accountants’ Report set out in Appendix I to this document, and there is no event since December 31, 2022 that would materially affect the information contained in the Accountants’ Report set out in Appendix I to this document.

DEFINITIONS

In this document, unless the context otherwise requires, the following terms and expressions shall have the meanings set forth below. Certain other terms are explained in “Glossary of Technical Terms.”

“Accountants’ Report”	the accountants’ report from the reporting accountants of the Company, Deloitte Touche Tohmatsu, the text of which is set out in Appendix I to this document
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council of Hong Kong
“AFRCO”	the Accounting and Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Articles of Association” or “Articles”	the articles of association of the Company conditionally adopted on November 11, 2022 and further amended, approved and adopted on June 2, 2023 with effect from the [REDACTED], as amended, supplemented or otherwise modified from time to time, a summary of which is set out in “Appendix V – Summary of Articles of Association” to this document
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of our Board
“Board” or “Board of Directors”	the board of Directors of the Company
“Business Day”	a day on which banks in Hong Kong are generally open for normal business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong
“CAGR”	compound annual growth rate

DEFINITIONS

“Caizhi No. 2”

Nanjing Caizhi No. 2 Enterprise Management Partnership (Limited Partnership) (南京才智二號企業管理合夥企業 (有限合夥)), a limited partnership established in the PRC on August 27, 2021 and one of our employee incentive platforms

[REDACTED]

DEFINITIONS

[REDACTED]

“China” or “PRC”	the People’s Republic of China excluding, for the purpose of this document, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“close associate(s)”	has the meaning ascribed to it under the Listing Rules
“ClinicalTrials.gov”	a registry of clinical trials run by the United States National Library of Medicine at the National Institutes of Health, and is the largest clinical trials database in the world
“CMS”	China Medical System Holdings Limited (康哲藥業控股有限公司), an exempted company incorporated in Cayman Islands with limited liability on December 18, 2006 and listed on the Stock Exchange (stock code: 00867)
“CNIPA”	China National Intellectual Property Administration (國家知識產權局)
“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

DEFINITIONS

“Company,” “our Company” or “the Company”	Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司), a joint stock company established in the PRC with limited liability on January 13, 2022, or, where the context requires (as the case may be), its predecessor, Wuhan YZY Biopharma Limited Company (武漢友芝友生物製藥有限公司), a limited liability company established in the PRC on July 8, 2010
“Compliance Adviser”	Gram Capital Limited
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules
“core connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Core Product”	M701, the designated “core product” as defined under Chapter 18A of the Listing Rules
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix 14 to the Listing Rules
“CSDC”	China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司)
“CSPC”	CSPC Pharmaceutical Group Limited (石藥集團有限公司), a limited liability company incorporated in Hong Kong on June 16, 1992 and listed on the Stock Exchange (stock code: 01093)
“CSPC-NBP”	CSPC NBP Pharmaceutical Co., Ltd. (石藥集團恩必普藥業有限公司), a limited liability company incorporated in the PRC on April 23, 2003, which was owned as to 54.06% and 45.94% by CSPC and Dragon Merit Holdings Limited, respectively, as of the Latest Practicable Date. For more details on the shareholdings of CSPC-NBP, please refer to the section headed “History, Development and Corporate Structure” in this document
“CSPC Group”	CSPC and its subsidiaries
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)

DEFINITIONS

“Director(s)” or “our Director(s)”	the director(s) of the Company
“Domestic Share(s)”	ordinary share(s) in the share capital of the Company with a nominal value of RMB1.00 each, which is/are [REDACTED] and paid up in Renminbi and are [REDACTED] Shares which are currently not [REDACTED] or traded on any stock exchange
“EIT”	enterprise income tax
“EIT Law”	Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the Government of Hong Kong
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Frost & Sullivan Report”	the report commissioned by the Company and independently prepared by Frost & Sullivan, a summary of which is set forth in “Industry Overview”

[REDACTED]

“Group”, “our”, “our Group”, “we” or “us”	the Company and its subsidiaries
“H Share(s)”	ordinary share(s) in the ordinary share capital of the Company, with a nominal value of RMB1.00 each, which are to be [REDACTED] and [REDACTED] in Hong Kong dollars and for which an [REDACTED] has been made for the granting of [REDACTED] and permission to [REDACTED] on the Stock Exchange

DEFINITIONS

[REDACTED]

“HK\$” or “HK dollars”

Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

“Hong Kong” or “HK”

the Hong Kong Special Administrative Region of the PRC

[REDACTED]

“Hong Kong Stock Exchange” or
“Stock Exchange”

The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited

[REDACTED]

“ICH”

the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

DEFINITIONS

“IFRS”	International Financial Reporting Standards, which include standards, amendments and interpretations promulgated by the International Accounting Standards Board (IASB) and the International Accounting Standards (IAS) and interpretations issued by the International Accounting Standards Committee (IASC)
“independent third party(ies)”	entity(ies) or person(s) which, to the best of our Directors’ knowledge, information, and belief having made all reasonable enquiries, is/are not a connected person(s) of the Company within the meaning of the Listing Rules

[REDACTED]

“Latest Practicable Date”	June 4, 2023, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

[REDACTED]

DEFINITIONS

“Listing Committee”	the listing committee of the Stock Exchange
[REDACTED]	
“Listing Rules” or “Hong Kong Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“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
“Ministry of Finance” or “MOF”	the Ministry of Finance of the PRC (中華人民共和國財政部)
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“Nanjing Youbodi”	Nanjing Youbodi Biotechnology Co., Ltd (南京友博迪生物技術有限公司), a limited liability company established in the PRC on December 29, 2020 and a wholly-owned subsidiary of the Company
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“Nomination Committee”	the nomination committee of our Board
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

DEFINITIONS

[REDACTED]

“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC Company Law”	the Company Law of the PRC (《中華人民共和國公司法》), as amended and adopted by the Standing Committee of the Eighth National People’s Congress on December 29, 1993 and effective on July 1, 1994, which was last amended and became effective on October 26, 2018, as amended, supplemented or otherwise modified from time to time
“PRC Government”	the central government of the PRC, including all governmental subdivisions (including principal, municipal and other regional or local government entities) and instrumentalities thereof or, where the context requires, any of them
“PRC Legal Advisor”	Jingtian & Gongcheng, our legal advisor as to PRC laws

DEFINITIONS

“[REDACTED] Investment(s)”	the investment(s) in the Company undertaken by the [REDACTED] Investors, the details of which are set out in “History, Development and Corporate Structure”
“[REDACTED] Investor(s)”	the investor(s) from whom the Company obtained several rounds of investments, the details of which are set out in “History, Development and Corporate Structure”

[REDACTED]

“Province”	each being a province or, where the context requires, a provincial-level autonomous region or municipality under the direct supervision of the central government of the PRC
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration Committee”	the remuneration committee of our Board
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“SAFE”	the State Administration of Foreign Exchange of the PRC (中國國家外匯管理局)
“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國市場監督管理總局), formerly known as the State Administration for Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局)
“SAT”	the State Administration of Taxation of the PRC (中國國家稅務總局)

DEFINITIONS

“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“SFC”	the Securities and Futures Commission of Hong Kong
“Share(s)”	ordinary share(s) in the share capital of the Company with a nominal value of RMB1.00 each, comprising the [REDACTED] Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“Shijiazhuang Shiyong”	Shijiazhuang Shiyong Biotechnology Co., Ltd (石家莊石友生物技術有限公司), a limited liability company established in the PRC on April 21, 2020 and a wholly-owned subsidiary of the Company

[REDACTED]

“Sophisticated Investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL92-18 issued by the Stock Exchange

[REDACTED]

“State Council”	the State Council of the PRC (中華人民共和國國務院)
“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)”	member(s) of our Supervisory Committee
“Supervisory Committee”	the supervisory committee of the Company

DEFINITIONS

“Takeovers Code”	the Codes on Takeovers and Mergers and Share Buy-back issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Track Record Period”	the periods comprising the two financial years ended December 31, 2021 and 2022
“Trial Measures”	the Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》), which was released by the CSRC and became effective on March 31, 2023

[REDACTED]

“[REDACTED] Foreign Share(s)”	ordinary share(s) issued by the Company with a nominal value of RMB1.00 each which is/are held by foreign investors and not [REDACTED] on any stock exchange
“[REDACTED] Share(s)”	Domestic Shares and [REDACTED] Foreign Shares
“U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. dollar” or “US\$”	United States dollar, the lawful currency of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended and supplemented or otherwise modified from time to time, and the rules and regulations promulgated thereunder

[REDACTED]

“WIV”	Wuhan Institute of Virology, Chinese Academy of Sciences

DEFINITIONS

“Wuhan Caizhi”	Wuhan Caizhi Investment Management Partnership (Limited Partnership) (武漢才智投資管理合夥企業(有限合夥)), a limited partnership established in the PRC on September 21, 2015
“Wuhan Youwei”	Wuhan Youwei Biotechnology Co., Ltd (武漢友微生物技術有限公司), a limited liability company established in the PRC on March 22, 2021 and a wholly-owned subsidiary of the Company
“%”	per cent

For ease of reference, the names of Chinese laws and regulations, governmental authorities, institutions, natural persons or other entities (including certain of our subsidiaries) have been included in this document in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail.

For the purpose of this document, references to “provinces” of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous regions.

Certain amounts and percentage figures included in this document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain technical terms used in this document in connection with us and our business. These may not correspond to standard industry definitions and may not be comparable to similar terms adopted by other companies.

“AE(s)”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrences in a patient administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“affinity”	the extent or fraction to which a drug binds to receptors at any given drug concentration or the firmness with which the drug binds to the receptor. Affinity describes the strength of the attraction between two chemicals, or an antigen and an antibody
“age-related disease(s)”	a disease that is most often seen with increasing frequency with increasing senescence
“age-related macular degeneration” or “AMD”	an irreversible medical condition of partial or complete vision loss caused by degenerative lesions of the retinal pigment epithelium and neuronal retina
“AL”	aluminum hydroxide adjuvant, aluminum hydroxide that is used to increase the efficacy or potency of certain vaccines
“ANG2”	angiopoietin-2, part of a family of vascular growth factors that play a role in embryonic and postnatal angiogenesis
“angiogenesis”	the formation and remodeling of new blood vessels and capillaries from growth of pre-existing blood vessels
“antibody-dependent cell-mediated cytotoxicity” or “ADCC”	an immune mechanism through which Fc gamma receptor-bearing effector cells can kill target cells expressing tumor- or pathogen-derived antigens on their surface through antibody-binding effect
“anti-angiogenic drugs”	targeted drugs with the main function of inhibiting tumor angiogenesis, inhibiting tumor growth, and reducing tumor metastasis

GLOSSARY OF TECHNICAL TERMS

“antibody-dependent cell-mediated phagocytosis” or “ADCP”	the mechanism by which antibody-bound target cells activate the Fc gamma receptors on the surface of phagocytes to induce phagocytosis, resulting in endocytosis and degradation of the target cell through phagosome acidification
“antigen”	molecule that stimulates an immune response by activating lymphocytes
“apoptosis”	programmed cell death, a genetically directed process of cell self-destruction that is marked by the fragmentation of nuclear DNA
“assay”	an analysis done to determine (i) the presence of a substance and the amount of that substance and (ii) the biological or pharmacological potency of a drug
“BLA”	biologics license application
“bispecific antibody” or “BsAb”	an antibody directed at two different targets or two different epitopes on the same target
“BOR”	best of response, the best response recorded from the start of the study treatment until the end of treatment taking into account any requirement for confirmation
“CAF”	cancer-associated fibroblast
“carcinoma”	a malignant tumor of epithelial origin
“CAR-T”	Chimeric Antigen Receptor T-Cell Immunotherapy, a therapy that uses T cells engineered with chimeric antigen receptors for cancer treatment
“CD3”	cluster of differentiation 3, a protein complex and T cell co-receptor that is involved in activating the cytotoxic T cell and T helper cells
“CD38”	cluster of differentiation 38, a glycoprotein expressed at low levels on normal healthy tissues, while at high levels on MM and lymphoma cells, functioning either as a receptor or as an enzyme

GLOSSARY OF TECHNICAL TERMS

“CDMO(s)”	contract development and manufacturing organization, which is a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“cell line”	a population of cells that 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
“cGMP” or “Current Good Manufacturing Practice”	current Good Manufacturing Practice (GMP) regulations enforced by the FDA that provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories
“CH”	the constant domain of the heavy chain of an antibody
“CH1”	the first constant domain of the heavy chain of an antibody
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“CHO”	Chinese hamster ovary, the ovary of a small rodent called the Chinese hamster
“CHO cell(s)”	Chinese hamster ovary cell(s)
“CIK(s)”	cytokine-induced killer cell(s)
“CL”	the constant domain of the light chain of an antibody

GLOSSARY OF TECHNICAL TERMS

“clinical trial”	a research study for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“Cmax”	the highest concentration of a drug in the blood, cerebrospinal fluid, or target organ after a dose is given and before a second dose is given
“CMC”	chemistry, manufacturing and controls activities in the development, licensure, manufacturing and ongoing marketing of pharmaceutical products
“CMO(s)”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“complement-dependent cytotoxicity” or “CDC”	the mechanism by which antibody-coated target cells recruit and activate components of the complement cascade, leading to the formation of a complex of attack on membranes on the cell surface and subsequent cell lysis
“compound(s)”	a substance formed by two or more ingredients in union
“COVID-19”	coronavirus disease 2019, a disease caused by the SARS-CoV-2 virus which may cause severe acute respiratory syndrome in humans
“CR”	complete response, which means that all target lesions have disappeared during the course of treatment. For MA treatment, it means complete disappear of ascites for at least four weeks based on CT evaluation. For MPE treatment, it means the volume of pleural effusion of no greater than 50ml for at least four weeks based on CT evaluation

GLOSSARY OF TECHNICAL TERMS

“CRO(s)”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research and development services outsourced on a contractual basis
“CRVO”	central retinal vein occlusion, a type of retinal vein occlusion (RVO), an occlusion of the main retinal vein posterior to the lamina cribrosa of the optic nerve and is typically caused by thrombosis
“CSO(s)”	contract sales organization, a company primarily engaged in providing sales representatives to promote and detail pharmaceutical products
“CT”	computed tomography, a medical-imaging technique used to obtain detailed internal images of the body
“cytokine release syndrome”	an acute systemic inflammatory syndrome characterized by fever and multiple organ dysfunction that is associated with therapeutic antibodies, CAR-T therapy, and haploidentical allogeneic transplantation
“cytokine(s)”	a broad and loose category of small proteins that are important in cell signaling, whose release has an effect on the behavior of cells expressing corresponding receptors
“cytotoxic”	toxic to living cells, causing cell damage or death
“dendritic cell(s)” or “DC(s)”	cells that constantly sample their surroundings for pathogens such as viruses and bacteria, detect dangers, and initiate immune responses. Immature dendritic cells have high endocytic activity and a low T-cells activation potential. Contact with a pathogen induces maturation and the expression of certain cell-surface molecules, greatly enhancing their ability to activate T cells
“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
“DLT”	dose-limiting toxicity, side effects of a drug or other treatment that are serious enough to prevent an increase in the dose of that treatment in clinical trial

GLOSSARY OF TECHNICAL TERMS

“DME”	diabetic macular edema, a serious eye complication characterized by abnormal swellings (edema) in the central part of the retina caused by tiny bulges protruding from the vessel walls, leaking, or oozing fluid and blood into the retina
“DOR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“drug product” or “DP”	a finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients
“drug substance” or “DS”	an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient
“EC50”	half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum
“EMT”	epithelial-mesenchymal transition, a process by which epithelial cells lose their cell polarity and cell–cell adhesion, and gain migratory and invasive properties to become mesenchymal stem cells
“EMT-6”	an epithelial tumor cell line that was isolated from the breast of a mouse with a mammary tumor
“EpCAM”	epithelial cell adhesion molecule, a type I transmembrane glycoprotein which plays a role in epithelial carcinogenesis and is involved in various biological functions, such as cell cycle progression, cell proliferation, differentiation, and migration, and immune evasion
“epitope(s)”	the specific part of an antigen to which an antibody attaches itself

GLOSSARY OF TECHNICAL TERMS

“Fab”	antigen-binding fragment, a region on an antibody that binds to antigens, consisting of a light chain and a VH and a CH1 of the heavy chain
“FACS”	fluorescence activated cell sorter, a specialized type of flow cytometry that uses fluorescent markers to target and isolate cell groups
“Fc”	crystallizable fragment, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
“FcγR”	Fc-gamma receptors, a receptor for the Fc region of immunoglobulin
“FDA”	the Food and Drug Administration of the United States
“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
“fusion protein”	proteins consisting of at least two domains that are encoded by separate genes
“Fv”	the smallest binding unit of an antibody which consists of a light-and heavy-chain variable domain
“GMP”	good manufacturing practices, a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products
“GMT(s)”	geometric mean titer, a measurement of the potency and immunogenicity of a vaccine
“Grade”	term used to refer to the severity of adverse events, using Grade 1, Grade 2, Grade 3, etc.

GLOSSARY OF TECHNICAL TERMS

“granzyme”	serine proteases released by cytoplasmic granules within cytotoxic T cells and NK cells
“hACE2”	human angiotensin converting enzyme II
“HCC”	hepatocellular carcinoma, a type of cancer arising from hepatocyte malignant transformation
“heavy chain(s)”	the large polypeptide subunit of an antibody
“HER2”	human epidermal growth factor receptor 2
“heterodimer(s)”	a protein composed of two polypeptide chains differing in the sequence, number, and kind of their amino acid residues
“hIgG1”	human immunoglobulin G1
“homodimer(s)”	a protein composed of two polypeptide chains that are identical in the sequence, number, and kind of their amino acid residues
“hormone therapy”	the use of hormone-based drugs to control or treat a certain disease or type of disease
“hPD-L1”	human programmed death ligand 1 (PD-L1)
“HPV”	human papillomavirus, a deoxyribonucleic acid (DNA) virus that has many types. HPV is an important cause of cervical cancer and is also associated with other types of genital cancer
“IFN- γ ”	interferon gamma, a dimerized soluble pro-inflammatory cytokine
“IgG”	immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
“IgG1”	immunoglobulin G1, a subclass of IgG
“IL”	interleukin, a type of cytokine and signaling molecule in the immune system to provoke an immune response in the body of a human or other animals

GLOSSARY OF TECHNICAL TERMS

“IL-2”	interleukin-2, a cytokine with essential roles the immune system, primarily via its direct effects on T cells
“IMiDs”	immunomodulatory drugs, drugs that regulate cellular and humoral immune functions and can enhance immune function, such as Lenalidomide
“immune checkpoint inhibitor(s)”	a type of drugs that block the immune evasion of tumor cells by certain molecules, which help promote immune responses and allow immune cells to kill cancer cells
“immunogenicity”	the ability of a particular substance, such as an antigen or epitope, to provoke an immune response in the body of a human and other animal. In other words, immunogenicity is the ability to induce humoral and/or cell-mediated immune responses
“immunosuppressants”	chemical drugs that inhibit abnormal immune responses in the body and are mainly used in clinical practice to treat inflammatory or autoimmune diseases
“immunotherapy”	a type of therapy that involves the immune system to help the body fight cancer, infection, and other diseases
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the United States.
“indication”	a symptom or particular circumstance that indicates the advisability or necessity of a specific medical treatment or procedure
“inhibitor”	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“intramuscular injection”	the injection of a substance into a muscle
“intraperitoneal injection”	the injection of a substance into the peritoneum (body cavity)
“intravenous injection”	an injection of a substance into a vein and directly into the bloodstream

GLOSSARY OF TECHNICAL TERMS

“intravitreal injection”	the injection of a substance into the vitreous cavity of the eye
“ <i>in vitro</i> ”	Latin for “within the glass,” studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
“ <i>in vivo</i> ”	Latin for “within the living,” studies in which the effects of various biological or chemical substances are tested on whole, living organisms as opposed to a partial or dead organism, or those done <i>in vitro</i>
“Knobs-into-Holes” or “KIH”	a technology which involves engineering the CH3 domains of antibodies to create a “knob” in one of the two heavy chains and a “hole” in the other heavy chain to promote heterodimerization
“laser photocoagulation”	a type of laser surgery, which mainly utilizes the photothermal effect of laser on tissues to locally heat up the target tissue after absorbing laser energy, causing the protein in the tissue to denature and solidify
“light chain(s)”	the small polypeptide subunit of an antibody
“local therapy”	the topical use of drugs to treat lesions
“lymphocyte(s)”	a subtype of white blood cells, such as T cells, B cells and NK cells
“malignant ascites” or “MA”	the accumulation of fluid in the peritoneal cavity resulting from the growth of primary or metastatic malignant neoplasms in the peritoneum
“malignant pleural effusion” or “MPE”	the collection of fluid in the pleural cavity resulting from malignant disease. Malignant pleural effusions often contain free floating malignant cells
“macrophage(s)”	a type of white blood cell that plays a role to phagocytose antigens, removes dead cells, and stimulates the action of other immune system cells
“MAD”	maximum administered dose, the highest dose that is safe to be administered to patients

GLOSSARY OF TECHNICAL TERMS

“MDSCs”	myeloid-derived suppressor cells, a diverse population of immature myeloid cells that have potent immune-suppressive activity
“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
“MM”	multiple myeloma, a cancer of the plasma cells in the bone marrow
“monoclonal antibody” or “mAb”	an antibody made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are made from hundreds of different immune cells
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“mOS”	median overall survival, the length of time from either the date of diagnosis or the start of treatment for a disease that half of the patients in a group of patients diagnosed with the disease are still alive
“MsAb”	multi-specific antibody
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“naïve”	not having received therapy
“NDA”	new drug application, a process required by a regulatory authority to approve a new drug for sale and marketing
“neovascularization”	the natural formation of new blood vessels
“NK cells”	natural killer cells, a type of cytotoxic lymphocyte, which provides rapid responses to virus-infected cell and other intracellular pathogens, and respond to tumor formation
“NOD/SCID mice”	non-obese diabetic/severe combined immunodeficient mice, a brand of immunodeficient laboratory mice
“NRDL”	the National Reimbursement Drug List of China
“NSCLC”	non-small cell lung cancer

GLOSSARY OF TECHNICAL TERMS

“objective response rate” or “ORR”	the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, a length of time that a patient with a specific disease is still alive, used as a measurement of a drug’s effectiveness
“PBM(s)”	peripheral blood mononuclear cell(s)
“PCD”	programmed cell death, a controlled mechanism that eliminates specific cells under developmental or environmental stimuli
“PCT”	Patent Cooperation Treaty, an international patent law treaty, which provides a unified procedure for filing patent applications to protect inventions in each of its contracting states
“PD-1”	programmed death 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”	programmed death ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“perforin”	a glycoprotein responsible for pore formation in cell membranes of target cells
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse
“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug

GLOSSARY OF TECHNICAL TERMS

“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“Phase I clinical trial”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“Phase II clinical trial”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“Phase III clinical trial”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“Photo-dynamic therapy” or “PDT”	a treatment method that combines photosensitizers and corresponding light sources to selectively destroy target tissues through photodynamic reactions. It has been widely used in the treatment of various surface tumors, such as multiple myeloma
“pivotal trial”	the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“placebo”	any dummy medical treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
“pleural sclerosis”	pathological tissues composed of fibrous connective tissue, appearing grayish white with granulation tissue on the surface caused by pleural thickening due to pleurisy
“PIs”	protease inhibitor, a class of compounds that inhibit the activity of protein kinases

GLOSSARY OF TECHNICAL TERMS

“pre-clinical studies”	studies or programs testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetics and safety information and to decide whether the drug is ready for clinical trials
“PR”	partial response, refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to the Response Evaluation Criteria in Solid Tumors. For MA and MPE treatment, it means at least 50% reduction in the volume of fluid (ascites or pleural effusion) for at least four weeks based on CT evaluation
“PRNT50”	the concentration of serum to reduce the number of plaques by 50% compared to the serum-free virus, a measure that tells how much antibody is present or how effective it is
“PuFS”	puncture-free survival, a length of time to first need for therapeutic puncture or death after treatment, whichever occurs first
“Q3W”	every three weeks
“QA”	quality assurance
“QC”	quality control
“RBD”	receptor-binding domain, a key part of a virus located on its “spike” domain that allows it to dock to body receptors to gain entry into cells and lead to infection
“recombinant”	the combination of genetic materials from more than one origin, or a method to express native proteins <i>in vitro</i> by genetic engineering
“refractory”	when used in reference to any type of cancer, cancer that does not respond to treatment. The cancer may be resistant at the beginning of treatment, or it may become resistant during treatment

GLOSSARY OF TECHNICAL TERMS

“relapsed”	when used in reference to any disease, including cancer, the return of a disease or the signs and symptoms of a disease after a period of improvement. With respect to cancer, the likely relapse occurs because a few of the original cancer cells survived the initial treatment. Sometimes, this occurs because cancer cells spread to other parts of the body and were too small to be detected during the follow-up immediately after treatment
“RM(s)”	rhesus macaque(s)
“RP2D”	recommended Phase II dose
“rrMM”	relapsed/refractory multiple myeloma
“RVO”	retinal vein occlusion, caused by a blockage of the veins carrying blood away from the retina of the eye, which can lead to macular edema where fluid becomes trapped within and under the retina, leading to rapid and severe loss of visual acuity
“SAE(s)”	serious adverse events, any medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect; or requires intervention to prevent permanent impairment or damage
“salt-bridge”	a combination of amino acids with opposite charge through hydrogen bonding and ionic bonding
“SARS-CoV-2”	severe acute respiratory syndrome coronavirus 2, a strain of coronavirus that causes COVID-19
“scFv”	single-chain variable fragment, a fusion protein of the variable regions of the heavy (VH) and light chains (VL) of immunoglobulins, connected with a protein linker peptide
“SCLC”	small cell lung cancer

GLOSSARY OF TECHNICAL TERMS

“second-line”	with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately
“sdAb” or “single-domain antibody”	an antibody which only includes heavy chain variable domains to bind to the antigen. In other words, this antibody only includes heavy chains
“SHRM”	subretinal hyperreflective material, a hyperreflective material seen on optical coherence tomography and located under the retina and above the retinal pigment epithelium
“SINE”	selective inhibitors of nuclear export, drugs that block exportin 1, a protein involved in transport from the cell nucleus to the cytoplasm.
“SMO(s)”	site management organization, an organization that provides clinical trial-related services
“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
“SPR”	surface plasmon resonance, a label-free technology that can measure sequential binding events and is a key part of any analytical toolbox, enabling the examination of dual-target specificities in a bispecific antibody within a single assay
“S protein”	spike glycoprotein, the largest of the four major structural proteins found in coronaviruses
“symmetric tetravalent BsAb(s)”	a tetravalent BsAb with symmetric structure that can target two different targets at the same time and is bivalent to each target
“systematic treatment”	any type of cancer treatment that has effects throughout the body rather than being applied directly to the cancer

GLOSSARY OF TECHNICAL TERMS

“T cell(s)”	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 cell-engaging BsAb(s)”	BsAb that binds TAA on cancer cells and targets on T cells with their two arms, thereby engaging effective T cells and tumor cells
“ $t_{1/2}$ ” or “half-life”	the period of time required for the concentration or amount of a drug in the body to be reduced to exactly one-half of a given concentration or amount of such drug
“TAM”	tumor-associated macrophage
“TCM”	traditional Chinese medicine
“TCR”	T cell antigen recognition receptor
“TEAE(s)”	treatment emergent adverse events, an event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state
“TGF- β ”	transforming growth factor- β , a versatile cytokine usually overexpressed in advanced tumors and related to poor prognoses
“TGF- β 1”	transforming growth factor beta 1, a polypeptide member of the TGF- β superfamily of cytokines
“TKI”	tyrosine kinase inhibitors, a pharmaceutical drug that inhibits tyrosine kinases
“TME”	tumor microenvironment, the ecosystem that surrounds a tumor inside the body which includes immune cells, the extracellular matrix, blood vessels and other cells, like fibroblasts. A tumor and its microenvironment constantly interact and influence each other, either positively or negatively
“TNF α ”	tumor necrosis factor- α , a cell signaling protein (cytokine) involved in systemic inflammation and one of the cytokines that make up the acute phase reaction

GLOSSARY OF TECHNICAL TERMS

“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals. It is expressed generally as a dose response
“TRAE(s)”	treatment-related adverse events
“Treg(s)”	regulatory T cell, a subpopulation of T cells that modulate the immune system, maintain tolerance to self-antigens, and prevent autoimmune disease
“tumor-associated antigen(s)” or “TAA(s)”	an antigen molecule present on tumor cells and normal cells which has been widely used for treating tumors
“TV”	tumor volume
“wAMD”	wet age-related macular degeneration (AMD), an irreversible medical condition of partial or complete vision loss caused by degenerative lesions of the retinal pigment epithelium and neuronal retina where abnormal blood vessel growth stimulated by VEGF under the macula causes blood and fluid to seep into the retina
“variants of concern” or “VOCs”	a category used for variants of SARS-CoV-2, being linked to rapid spread in human populations (epidemiological data)
“VEGF”	vascular endothelial growth factor, a family of signaling protein critical for the growth of the new vessels and thereby development of cancer cells. VEGF, including VEGF-A, VEGF-B, VEGF-C and VEGF-D, binds to VEGF receptors (VEGFRs), generally, VEGF-A is referred to as VEGF unless otherwise specified
“VL”	the variable domain of the light chain of an antibody
“VH”	the variable domain of the heavy chain of an antibody
“VHH”	also known as a nanobody, is the variable domain of the heavy chain of a single-domain antibody

FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements that relate to our current expectations and views of future events. These forward-looking statements are contained principally in “Summary,” “Risk Factors,” “Industry Overview,” “Business,” “Financial Information” and “Future Plans and Use of [REDACTED].” You are strongly cautioned that these statements relate to events that involve known and unknown risks, uncertainties and other factors, including those listed in “Risk Factors”, which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, these forward-looking statements can be identified by words or phrases such as “may,” “will,” “expect,” “anticipate,” “aim,” “estimate,” “intend,” “plan,” “believe,” “potential,” “continue,” “is/are likely to” or other similar expressions. These forward-looking statements include, among other things, statements relating to:

- our operations and business prospects;
- our financial condition and performance;
- our future debt levels and capital expenditure plan;
- our ability to complete the development and obtain the relevant requisite regulatory approvals of our drug candidates;
- our ability to commercialize our approved products in a timely manner;
- future developments, trends and conditions in the industries and markets in which we operate or plan to operate;
- general economic, political and business conditions in the markets in which we operate;
- changes to the political and regulatory environment in the industries and markets in which we operate;
- the effects of the on-going COVID-19 pandemic;
- the actions and developments of our competitors;
- the ability of third parties to perform in accordance with contractual terms and specifications;
- our ability to retain senior management and key personnel and recruit qualified staff;
- our business strategies and plans to achieve these strategies;

FORWARD-LOOKING STATEMENTS

- our ability to defend our intellectual rights and protect confidentiality;
- the effectiveness of our quality control systems;
- change or volatility in interest rates, foreign exchange rates, equity prices, trading volumes, commodity prices and overall market trends, including those pertaining to the PRC and the industry and markets in which we operate;
- capital market developments; and
- changes on the fair valuation of our biological assets.

These forward-looking statements are subject to risks, uncertainties and assumptions, some of which are beyond our control. In addition, these forward-looking statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual outcomes may differ materially from the information contained in the forward-looking statements as a result of a number of factors, including, without limitation, the risk factors set forth in “Risk Factors”.

The forward-looking statements made in this document relate only to events or information as of the date on which the statements are made in this document. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this document completely and with the understanding that our actual future results or performance may be materially different from what we expect.

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

RISK FACTORS

An investment in our H Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to invest in our H Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the [REDACTED] of our H Shares could decline, and you may lose all or part of your investment. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-Looking Statements” in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the research and development of our drug candidates; (ii) risks relating to our financial position and need for additional capital; (iii) risks relating to commercialization of our drug candidates; (iv) risks relating to manufacturing of our drug candidates; (v) risks relating to our intellectual property rights; (vi) risks relating to our reliance on third parties; (vii) risks relating to extensive government regulations; (viii) risks relating to our operations; (ix) risks relating to doing business in China; and (x) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also have a material adverse effect on our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

Our ability to generate revenue and become profitable are substantially dependent on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. We have designed and developed a pipeline of seven clinical-stage drug candidates. We have invested a significant portion of our efforts and resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates.

RISK FACTORS

The success of our drug candidates will depend on several factors, including but not limited to:

- favorable safety, immunogenicity and efficacy data from our clinical trials and other studies;
- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- competition with other drug candidates and marketed drugs;
- obtaining sufficient supplies of any drug products or marketed drugs that are used in combination with our drug candidates, competitor drugs, or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- receipt of regulatory approvals from the NMPA, the FDA or other comparable regulatory authorities for our drug candidates;
- the capabilities and competence of our collaboration partners;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- establishing sufficient commercial manufacturing capabilities, either by constructing new facilities ourselves and/or making arrangements with qualified CMOs;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining favorable governmental and private reimbursement from third-party payers for our drugs, if and when approved;

RISK FACTORS

- continued acceptable safety profile of our drug candidates following regulatory approval, if and when received; and
- stable and supportive domestic policies, favorable international environment and good relationships among nations.

If we do not achieve one or more of the aforementioned factors in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and/or successfully commercializing our drug candidates, which would have a material adverse effect on our business, financial condition and results of operations.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods. For instance, patients with MA and/or MPE currently have limited treatment options and poor prognosis. Current treatments for MA have limited efficacy and certain risks, such as significant patient discomfort and declining efficacy with tumor progression, and current treatments for MPE are mainly palliative while seldom effective in increasing the survival rate. Our Core Product, M701, is designed to address the medical demands of MA and MPE patients, leveraging its mechanisms. However, there are inherent risks in the development of novel therapeutics, including M701 and our other drug candidates, which could result in delays in clinical development, regulatory approval or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approval and/or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for the regulatory approval. This may have a material impact on our ability to generate revenue from our drug candidates, which in turn may materially and adversely affect our business, financial condition and results of operations.

As of the Latest Practicable Date, all of our drug candidates were in various phases of clinical trials and pre-clinical studies and we did not have any drug candidates that are at NDA/BLA stage with the relevant competent regulatory authorities. We therefore do not yet have experience in filing for regulatory approval for our drug candidates, and we have not yet demonstrated the ability to receive regulatory approval for our drug candidates. As a result, our ability to successfully obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

We may not be able to identify, discover or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.

The success of our business depends upon our ability to identify, discover, develop and commercialize additional drug candidates. We cannot guarantee that we will be successful in identifying potential new drug candidates. Even if we succeeded in identifying new drug candidates, drug candidates that we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Some drug candidates such as BsAb drug candidates for oncology that we intend to identify could also be technically challenging to develop and manufacture. We may also pursue collaboration with third parties in the discovery and development of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results.

RISK FACTORS

Research programs to identify new drug candidates and drug targets or to pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Our research programs 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 but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;
- there may be a lack of transferability of experimental results obtained in the laboratory testing in cells or from animals into clinical treatment and safety outcomes in human subjects, including unexpected toxicities in humans;
- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired safety and efficacy;
- it may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio; or
- we may not be able to manufacture the right dosage form to match the appropriate route of administration during the development of our drug candidates.

Accordingly, there can be no assurance that we will be able to identify new drug candidates or additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially and adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

The development of BsAbs is a nascent field and faces many imminent risks and challenges.

BsAbs are produced through cellular expression techniques, typically incurring higher production costs than the synthesis technologies used for small molecule drugs. In addition, BsAbs cannot be administered orally, thus the less convenient administration methods of BsAbs, especially intravenous administration, increases treatment costs and safety risks associated with infusions.

Compared to monospecific antibodies, the design, research, and validation of the dual-specific binding mechanism of BsAbs, along with the molecular construction and preparation of BsAbs, are significantly more complex. This increases the difficulty and risk of developing BsAbs and the difficulty and cost of their production. Compared to cell therapies, BsAbs cannot replenish functional cells in the body. Therefore, in situations where there is a deficiency of functional cells in the body, BsAbs may not be able to achieve optimal therapeutic effects. In addition, BsAbs face intense competition from monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), multi-specific antibodies (MsAbs), and fusion protein antibodies, which may surpass BsAbs in terms of cost, research and development difficulty, success rate, and market acceptance. For example, the advantages and distinctive characteristics of fusion protein antibodies have led to considerable commercial success. Pharmaceutical giants such as Regeneron and Roche have generated substantial sales from fusion protein antibody drugs.

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We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts.

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, 2021 and 2022, our research and development expenses were RMB112.9 million and RMB157.3 million, respectively, accounting for approximately 78.2% and 88.5% of our operating expenses (being the research and development expenses and administrative expenses) for the same years, 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 research and development. 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 innovative drugs to market, obtain sufficient or any patent or other intellectual property protection for such new or innovative drugs, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such drugs are introduced to the market, that those drugs will achieve market acceptance. Any failure to do so may make our technologies obsolete, which could harm our business and prospects.

We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological changes. Major pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of drugs for the treatment of cancer and its complications, or other indications for which we are developing our drug candidates.

Some of our competitors have greater financial, technical and human resources, more established commercialization infrastructure as well as more drug candidates in late-stage clinical development than we do. For instance, M701 faces intense competition from various angles. Firstly, M701 faces competition from current medical treatment methods for MA and MPE, primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, which are less costly in nature. Among these current treatment options for MA and MPE, therapeutic paracentesis is recommended by clinical guidelines for controlling MA/MPE which can alleviate symptoms for one to two weeks. For details, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM × CD3 Targeted BsAb – Treatment Paradigm for MA and MPE in China” in this document. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis. However, this method will also be more expensive. We may face competition from less costly current treatment options for MA and MPE.

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In addition, M701 also faces competition from multiple peer products under development for the treatment of MA and MPE. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. Among them, catumaxomab (developed by TRION Pharma GmbH and Neovii Biotech GmbH) is the world’s first marketed BsAb and has two targets identical to M701 which was approved in 2009 for the treatment of MA. Upon the initial commercial launch of catumaxomab in 2009, based on public information, the medical community’s understanding of immunotherapy and BsAb was not fully developed, which limited the comprehension of the mechanism of actions of catumaxomab, resulting in a relatively cautious approach towards the clinical application of the drug. Moreover, based on public information, the developers of catumaxomab fell short in formulating a market-oriented marketing strategy for catumaxomab, which led to poor sales performance after its launch and its subsequent withdrawal from the market in 2017. Catumaxomab was marketed in Europe only and the withdrawal of catumaxomab only impacted the Europe market. The withdrawal of catumaxomab was primarily due to timing and sales strategy instead of safety and efficacy concerns. Despite of that, as the world’s first BsAb drug, the withdrawal of catumaxomab did impact the overall perception of BsAbs within the medical community for a period of time. However, this perception has gradually improved with the increase in marketed BsAb drugs and their clinical use. Catumaxomab demonstrated manageable safety and encouraging efficacy during its clinical use. Therefore, the developers of catumaxomab applied for the renewal of the EMA marketing authorization of the drug for the treatment of MA in August 2022, which is currently under review. In addition, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in a Phase III clinical trial for stomach neoplasms, advanced gastric carcinoma with peritoneal metastasis, and a Phase I/II clinical trial for non-muscle-invasive bladder cancer in China. Based on publicly available information, LintonPharm are developing catumaxomab in collaboration with LINDIS Biotech, a research partner of TRION Pharma GmbH. LINDIS Biotech is also evaluating catumaxomab in a Phase I clinical trial for urinary bladder neoplasms in German. Catumaxomab is expected to be available in China and Europe upon successful commercialization.

Moreover, M701 faces competition from peer products targeting identical molecular targets as M701. According to public information, there are BsAb pipelines targeting EpCAM and CD3 and mAb, antibody fusion protein and CAR-T pipelines targeting EpCAM currently under clinical development globally. As of the Latest Practicable Date, these competitors have not developed their EpCAM × CD3 drug candidates for the treatment of MA/MPE, however we cannot guarantee that these companies will not expand into our target market. Among them, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in clinical trials for advanced gastric cancer and for non-muscle invasive bladder cancer in China. Based on publicly available information, LintonPharm are developing catumaxomab in collaboration with LINDIS Biotech, a research partner of TRION Pharma GmbH. In the bladder cancer Phase I clinical trial sponsored by LintonPharm Co., Ltd., 6 participants received catumaxomab through intravesical instillation. After the first tumor evaluation, all participants achieved a complete response, with the duration of response lasting 9.5 months. In addition to the above pipelines, Amgen Inc. commenced a multicenter Phase I clinical trial of solitomab, a bispecific EpCAM×CD3 T-cell engager BsAb in patients with refractory solid tumors in 2008. According to public information, Amgen Inc. has removed solitomab from its pipeline update since 2015, indicating that it may have suspended the clinical development plan for the drug candidate. We have not learned from public information that solitomab has safety or effectiveness issues. Amgen’s suspension of this pipeline may be due to strategic considerations.

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Furthermore, we face indirect competition from other therapies for primary and metastatic cancers, including but not limited to chemotherapy, targeted therapies, and immunotherapies. These therapies, while not directly targeting MA and MPE, can help control these complications. Approximately 10% of patients with mild symptoms of MA and MPE only need these cancer therapies to control their MA and MPE. These therapies for cancer thereby indirectly limit the market size for M701. In addition, multiple companies, including large multi-national pharmaceutical companies, are also developing CD3 targeted BsAbs for hematological malignancies and solid tumors, including AbbVie Inc., Pfizer Inc., Johnson & Johnson and Roche Ltd, which, if successfully developed and subsequently approved for marketing, may compete with our CD3-targeted BsAbs. Even if our drug candidates have been successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, we will still face competition in terms of safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position. In addition, any new drug that competes with an approved drug must demonstrate compelling advantages in efficacy, immunogenicity, convenience, tolerability and/or safety in order to overcome price competition and to be commercially successful. Disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or noncompetitive.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis.

As of the Latest Practicable Date, all of our seven drug candidates were under clinical development in China. Commencement of a clinical trial is subject to finalizing trial design based on ongoing discussions with the NMPA, the FDA or other comparable regulatory authorities. We cannot assure you as to when the clinical trials for our drug candidates in discovery and pre-clinical stages will begin, if at all.

Successful completion of our clinical trials is a prerequisite to receiving BLA or similar approvals from the NMPA, the FDA or other comparable regulatory authorities for each drug candidate and, consequently, the ultimate commercialization of our drug candidates. As of the Latest Practicable Date, except for certain delays in our clinical trials due to the impact of COVID-19, none of our clinical trials had failed, been delayed or suspended. For more details, please refer to the paragraphs headed “Summary – Impact of the COVID-19 Outbreak” in this document. However, clinical trials are expensive, difficult to design and implement, and can take years to complete with uncertainty as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing.

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We may experience numerous unexpected events during, or as a result of, clinical trials that could delay us in or prevent us from receiving regulatory approvals for the development and commercialization of our drug candidates, including but not limited to situations whereby:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- 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;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- our drug candidates may lack meaningful clinical responses, which may expose the participants to unacceptable health and safety risks;
- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons such as non-compliance with regulatory requirements; and
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive 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, or obtain approval for proposed indications that are not as broad as intended. We may have the drug removed from the market even after obtaining regulatory approval. We may also be subject to additional post-marketing testing requirements and restrictions on how the drug is distributed or used. We may be unable to obtain reimbursement for use of the drug.

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Delays in clinical trials and other testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays could also shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may have an adverse effect on our business and results of operations.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to timely enroll a sufficient number of patients who opt to participate and remain in the trial until its conclusion. We may fail 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 our clinical trials as required by the NMPA, the FDA or similar regulatory authorities, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. The inability to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to:

- the design of the trial;
- the patient eligibility criteria defined in the protocol;
- the severity of the disease under investigation;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial’s primary endpoints;
- our ability to obtain and maintain patient consents;
- the experience and competencies of our third-party contractors such as our CROs and SMOs;
- our ability to select clinical trial sites and to recruit clinical trial investigators with the appropriate competencies and experience;
- the proximity of patients to trial sites;

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- clinicians’ and patients’ perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the outbreak of epidemics or pandemics, such as COVID-19; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients may opt to enroll in a trial conducted by one of our competitors instead of ours. As the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent completion of these trials and materially and adversely affect our ability to advance the development of our drug candidates.

Results of earlier studies and trials may not be predictive of future trial results.

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily predict successful final results. Our drug candidates in later stages of clinical trials may fail to show the desired safety, immunogenicity and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials.

In some instances, there can be significant variability in safety, immunogenicity and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. As drug candidates are developed through pre-clinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Constantly updated standard therapies may change patient resistance, which may affect the efficacy of our medicines. Such changes carry the inherent risks that they may not necessarily

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achieve the intended objectives. In addition, our future clinical trial results may differ from earlier trials and may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. If so, 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 and adversely affect our business, financial condition results of operations and prospects.

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 approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates for their proposed indications in humans. We may conduct clinical trials with larger subject sample sizes as our clinical trial plan advances, and our drug candidates may not show the promising safety, immunogenicity and efficacy results that were observed in earlier clinical trials with fewer subjects. Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay, suspend or terminate clinical trials and result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Adverse events 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 have other unexpected characteristics, such as short-term DOR and insufficient enhancement of overall survival benefits.

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, any or some of the following would occur:

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;
- we may be required to add labeling statements, such as a “boxed” warning or a contraindication;

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- we may be required to create a medication guide outlining the risks of the side effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy program, including but not limited to medication guides, doctor communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk management tools;
- we may not be able to obtain regulatory approvals for all the proposed indications as intended;
- we may be subject to restrictions on how the drug is distributed or used;
- we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates;
- we may be unable to obtain reimbursement for use of the drug; and
- conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

Having expended a significant amount of capital to progress our drug candidates, if such 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 not be able to realize any revenue on such drug candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

In addition, if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, it could result in a number of potentially significant negative consequences, including but not limited to, the following situations whereby:

- we may be forced to suspend marketing of the drug;
- regulatory authorities may withdraw approvals for the commercial sales of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;

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- we may be required to conduct post-market studies;
- we could be required to recall our products and be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Immune-oncology therapies, including immune checkpoint inhibitors, may cause undesirable side effects.

Immune-oncology therapies such as immune checkpoint inhibitors are still considered as emerging and relatively novel therapeutics for treating cancer. Their mechanisms of action are yet to be thoroughly understood, and adverse events or side effects have been observed in clinical studies and reported by medical practitioners in connection with their usage in cancer patients. In particular, we are developing a number of BsAb drug candidates for oncology, which represent innovative, next generation medical therapies. BsAb treatments are largely still under development, with numerous pre-clinical studies and clinical trials to determine their safety and efficacy in oncology. To date, only a few BsAbs have been approved for oncology treatments in the world.

The results of clinical trials for immune-oncology therapies, including immune checkpoint inhibitors and specifically, BsAb candidates, could reveal a high and unacceptable severity and prevalence of undesirable side effects, including TEAEs that may be treatment-related. Managing adverse events and toxicity for patients undergoing BsAbs treatments may be more complex. Any such side effects could adversely impact our ability to obtain regulatory approvals. For example, the NMPA, the FDA or other comparable regulatory authorities could order us to suspend or terminate the studies of or to cease further development of, or deny approval of, our drug candidates. These TEAEs may be more common in certain patient populations and may be exacerbated when immune checkpoint inhibitors are combined with other therapies. In addition, any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete trials or may result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our pre-clinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our products under development, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a patient, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. The insurance coverage for clinical trials may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on our collaboration partners and other third parties to monitor and manage data for some of our ongoing pre-clinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs, our collaboration partners or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those pre-clinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, please refer to the paragraphs headed “– Risks Relating to Our Reliance on Third Parties – We work with various third parties to develop our drug candidates, such as those who help us conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed” in this section.

RISK FACTORS

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on 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 financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. Accordingly, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we cannot 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 in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

The commercial potential for our Core Product, M701, may be limited as there are other low-cost treatment options available in the market for its targeted indications.

We are developing our Core Product, M701, for the treatment of MA and MPE. Currently, patients with MA and/or MPE have limited treatment options and poor prognosis. Although there are no established, evidence-based, universally accepted guidelines in treating MA and MPE globally, there are certain treatment options available in the market to manage MA and MPE which are usually low cost in nature, including but not limited to intra-peritoneal administered chemotherapy, diuretic treatment such as spironolactone, manual aspiration of MA and MPE. In addition, reimbursement by government authorities may be limited or not available for BsAbs solely for the treatment of MA and MPE, such as M701. If government reimbursement is not available or is available only to limited levels, patients may not be willing to pay out-of-pocket in the absence of the reimbursement by government authorities and our Core Product may fail to achieve sufficient market acceptance as expected, even if our Core Product is approved for commercial sales. As a result, we may not be able to generate significant revenue from the commercialization of M701 and our business, financial position, results of operations and prospects may be adversely affected.

Our market opportunities may also be limited by competitors’ treatments for MA and MPE that may enter the market. For details, please refer to the paragraphs headed “– Risks Relating to the Research and Development of Our Drug Candidates – We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.”

RISK FACTORS

In conducting drug discovery, development and commercialization, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources.

Liability claims may result in decreased demand for our drug candidates, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management’s time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, or labeling, marketing or promotional restrictions, loss of revenue, exhaustion of any available insurance and our capital resources, the inability to commercialize any approved drug candidate, and a decline in the [REDACTED] of our H Shares.

To cover such liability claims arising from clinical studies, we purchase clinical trial insurance to cover adverse events in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

Investment in the development of pharmaceutical products is highly speculative as it requires substantial upfront capital expenditures and involves significant risks that a drug candidate may fail to demonstrate efficacy or safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we had financed our operating activities primarily through capital contributions from our shareholders, private equity financing and bank loans.

RISK FACTORS

We had not generated any revenue from commercialization of our drug candidates during the Track Record Period, and had incurred, and may continue to incur, significant research and development expenses and other expenses related to our ongoing operations. For the years ended December 31, 2021 and 2022, we had loss and total comprehensive expenses of RMB148.5 million and RMB188.9 million, respectively. Our ability to generate significant revenue from our drug candidates will depend primarily on the success of the regulatory approval, manufacturing, and commercialization of the drug candidates, which is subject to significant uncertainty. Even if we obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our drug candidates, and our ability to achieve sufficient market acceptance.

We expect to continue to incur significant expenses and losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue to advance the clinical trials and pre-clinical studies of our drug candidates;
- initiate pre-clinical, clinical or other studies for new drug candidates;
- construct new manufacturing facilities;
- manufacture clinical trial materials through CMOs and CDMOs in and outside China;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize our drug candidates for which we have obtained marketing approvals;
- attract and retain skilled personnel, and grant equity-settled awards to our employees under our share incentive schemes;
- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- maintain, protect, expand and enforce our intellectual property portfolio;
- enforce and defend any intellectual property-related claims; and
- acquire or in-license other drug candidates, intellectual property assets and technologies.

RISK FACTORS

The amount of our future net losses will depend, in part, on our future expenses resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved drug candidates, our ability to generate revenues, and the timing and amount of milestone and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails during clinical trials or does not obtain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and shareholders’ equity.

We had cash outflow from operating activities during the Track Record Period and may continue to experience net operating cash outflow for the foreseeable future.

During the Track Record Period, our operations have consumed a substantial amount of cash. Net cash used in operating activities was RMB98.7 million and RMB176.7 million for the years ended December 31, 2021 and 2022, respectively. We expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations such as the payments under our agreements with third parties, be unable to meet our capital expenditure requirements, be forced to scale back our operations, and/or experience other negative impacts on our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We will need to obtain additional financing to fund our operations, and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates.

We may require additional cash resources to meet our continued operating cash requirements in the future, especially to fund our research and development activities. For the years ended December 31, 2021 and 2022, we had net cash outflows from operating activities of RMB98.7 million and RMB176.7 million, respectively. We expect to continue to spend substantial amounts of cash on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approval. If the financial resources available to us after the [REDACTED] are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

RISK FACTORS

Our results of operations, financial condition, and prospects may be adversely affected by fair value changes and credit risk associated with our financial assets at fair value through profit or loss.

During the Track Record Period, we had certain financial assets at fair value through profit or loss, including structure deposits and wealth management products managed by financial institutions in China. We recorded financial assets at fair value through profit or loss of RMB19.5 million and RMB47.0 million as of December 31, 2021 and 2022, respectively. For more details, please refer to the paragraphs headed “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position – Financial Assets at FVTPL” in this document. We are exposed to risks in relation to the financial assets, which may adversely affect our net changes in their fair value. The financial assets at fair value through profit or loss are stated at fair value, and net changes in their fair value are recorded as other gains or losses, and therefore directly affect our results of operations. We cannot assure you that market conditions and regulatory environment will create fair value gains and we will not incur any fair value losses on our financial assets at fair value through profit or loss in the future. If we incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

We have indebtedness and may incur additional indebtedness in the future, which may materially and adversely affect our financial condition and results of operations.

We maintained certain borrowings to finance our operations during the Track Record Period. We had bank borrowings of RMB28.0 million and RMB76.5 million as of December 31, 2021 and 2022, respectively. As of April 30, 2023, we had bank borrowings of RMB49.0 million. For more details, please refer to the paragraphs headed “Financial Information – Indebtedness – Bank Borrowings” in this document. We may incur additional indebtedness in the future and may not be able to generate sufficient cash to satisfy our existing and future debt obligations.

Our indebtedness could have a material adverse effect on us by, among others, increasing our vulnerability to adverse developments in general economic or industry conditions, such as significant increases in interest rates, and limiting our flexibility in making changes in our business and operations. Our borrowings may subject us to certain restrictive covenants which may restrict or otherwise adversely affect our operations. These covenants may restrict our ability to, among others, incur additional debt, provide loans or guarantees, provide security and quasi-security, incur liens, dispose of material assets through sale, lease or other methods, pay dividends or distributions on certain of our subsidiaries’ capital stock, repay or transfer certain indebtedness, reduce registered capital, make investments and acquisitions, establish joint ventures, conduct mergers, consolidation and other change-of-control transactions, and file for bankruptcy or dissolution. In addition, some of the loans may have restrictive covenants linked to our financial performance, such as maintaining a prescribed maximum debt-to-asset ratio or minimum profitability levels during the term of the loans.

RISK FACTORS

Moreover, certain of our borrowings were secured by our property, right-of-use assets and investment properties. For details, please refer to Note 24 in Appendix I to this document and the paragraphs headed “Financial Information – Indebtedness – Bank Borrowings” in this document. In the event that we default on payment obligations of the secured indebtedness or are unable to comply with the restrictions and covenants imposed by the loan agreements in our future debt obligations, banks could terminate their commitments to us, accelerate the payments and declare all amounts borrowed due and payable, enforce the security or terminate the loan agreements. If any of the foregoing events occurs, there can be no assurance that our assets and cash flow will be sufficient to repay all of our debts as they become due, or that we will be able to obtain alternative financing on commercially reasonable terms. Furthermore, if the banks enforce any security over our assets, our business, financial condition, results of operations and prospects would be materially and adversely affected.

We may be exposed to risks associated with our prepayments, deposit and other receivables.

Our prepayments, deposit and other receivables consist primarily of (i) prepayments for research and development services which were mainly related to upfront fees paid for research and development services for the clinical and non-clinical studies of our drug candidates; (ii) prepayments for [REDACTED] expenses and [REDACTED] costs; (iii) deferred [REDACTED] costs; and (iv) advance to staff. As of December 31, 2021 and 2022, our prepayments, deposit and other receivables amounted to RMB14.1 million and RMB27.8 million, respectively. We cannot assure you that we will be able to request the refund of prepayments or deposit if relevant parties delay or default in performing their obligations, or collect other receivables on time pursuant to the agreed payment schedule. The time frame and method for the refund may not be specified, and there may not be a mechanism in place to ensure that the refund will be made on a timely basis. Moreover, we may not be able to receive relevant parties’ payments in full, or at all. As a result, we may need to make provisions for prepayments, deposit and other receivables. The occurrence of such event may materially and adversely affect our financial condition and results of operations.

Share-based payment may cause shareholding dilution to our existing Shareholders and have a negative effect on our financial performance.

We established two employee incentive platforms, Wuhan Caizhi and Caizhi No. 2, in recognition of the contributions of certain eligible employees and directors. For further details, please refer to the paragraphs headed “History, Development and Corporate Structure – Employee Incentive Platforms” in this document. For the years ended December 31, 2021 and 2022, we incurred share-based payment expenses of RMB39.6 million and RMB1.6 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a negative effect on our financial performance.

RISK FACTORS

Fluctuations in exchange rates could result in foreign currency exchange losses.

The change in the value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies. Most all of our costs are denominated in RMB, most of our assets are cash and cash equivalents primarily denominated in RMB, and our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against RMB may adversely affect the value of and any dividends payable on, our H Shares in Hong Kong dollars. For example, a further appreciation of Renminbi against 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 Hong Kong dollars into Renminbi for such purposes. Conversely, if we decide to convert our Renminbi into Hong Kong dollars for the purpose of making payments for dividends on our H Shares or for other business purposes, appreciation of the Hong Kong dollar against Renminbi would have a negative effect on the Hong Kong dollar amount available to us.

RISKS RELATING TO COMMERCIALIZATION OF OUR DRUG CANDIDATES

We have limited experience in the commercialization of drugs. If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. Our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in launching and marketing drug candidates. We will be competing with many companies that currently have commercialization teams and extensive sales and marketing operations. With limited experience in sales and marketing, we may be unable to compete successfully against these more established companies.

In the long term, if we intend to distribute our products worldwide, we would need to develop and expand our in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

RISK FACTORS

If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

There can be no assurance that we will be able to successfully develop and maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for our drug candidates’ commercial success.

Our drug candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. Potential patients and their physicians may be inclined to use conventional standard-of-care treatments rather than trying out a novel approach. Further, given the novelty of our drug candidates, patients and medical personnel may need substantial education and training. In addition, physicians, patients and third-party payers may prefer other products to ours. If our drug candidates do not achieve an adequate level of acceptance, the commercialization of such drug candidates may become less successful or profitable than we had expected.

The degree of market acceptance of our drug candidates, if approved for commercial sales, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved and the market demand for approved products that treat those indications;
- efficacy and safety of our drug candidates;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- acceptance by physicians, operators of hospitals and clinics and patients of our products as a safe and effective treatment;
- product labeling or package insert requirements of regulatory authorities;

RISK FACTORS

- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive 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 payers and government authorities;
- price control or downward adjustment by the government authorities or other pricing pressure, including the price reduction during the negotiation for inclusion in the national reimbursement drug lists in the PRC;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- adverse publicity about our products or favorable publicity about competitive products; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, third-party payers or others in the medical community, we will not be able to generate significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if newly introduced products or technologies are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially and adversely affect our business, financial condition, results of operations and prospects.

RISK FACTORS

We may be unable to produce a successful COVID-19 vaccine and generate demand for our vaccine before the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is significantly diminished. Even if we are successful in producing a vaccine against COVID-19, we may need to devote significant resources to its scale-up and development.

Concurrently, a large number of vaccine manufacturers, academic institutions and other organizations are in the process of developing COVID-19 vaccine candidates. Our competitors pursuing COVID-19 vaccine candidates may have greater financial, development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their COVID-19 vaccine candidates.

Our efforts to develop Y2019 for regulatory approval and commercialization or generate demand for Y2019 may fail if our competitors develop and commercialize one or more COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, or are more convenient or are less expensive than any vaccine candidate that we may develop. Since late 2020, multiple SARS-CoV-2 variants including variants of concern have emerged. As such, since the COVID-19 pandemic continues to evolve in China and globally, the long-term effectiveness of, and the protection provided by, any marketed or development-stage COVID-19 vaccines against various SARS-CoV-2 strains continue to be evaluated in longitudinal studies.

Clinical trials for COVID-19 vaccines involve a lengthy and expensive process with an uncertain outcome. Given the severity and urgency of the COVID-19 pandemic, we have committed significant capital and resources to fund the development of Y2019. However, there are uncertainties surrounding the longevity and extent of the COVID-19 pandemic as a global health concern. The COVID-19 pandemic may have been controlled before we successfully commercialize a successful COVID-19 vaccine and obtain adequate market demand for our vaccine candidate and realize any return on our investment in the research and development of our vaccine candidate. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

Furthermore, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine candidate at potentially much greater expense and with longer timeframes for public distribution.

RISK FACTORS

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or not immediately available in the PRC or other countries for our drug candidates, and we may be subject to unfavorable pricing regulations, which may affect our profitability.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approvals of the sale price of a drug before marketing. In many countries, the pricing review period commences after marketing or licensing approvals are granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approvals are granted. As a result, we might obtain regulatory approvals for a drug in a particular country, but then be subject to price regulations that 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 approvals. For example, according to a statement, Opinions of the State Council on Reforming the Review and Approval System for Pharmaceutical Products and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》), issued by the PRC State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of a new drug in the PRC market shall not be higher than the comparable market prices of the product in its country of origin or PRC’s neighboring markets, as applicable.

The successful commercialization of our drugs also depends on the extent to which reimbursement for these drugs and related treatments will be available from relevant health administrative authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and healthcare organizations, decide which medications they will pay for and stipulate reimbursement levels. With the trend of cost containment in the global healthcare industry, government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. There are an increasing number of third-party payers requiring companies to provide them with predetermined discounts from list prices and challenging the prices charged for medical products. There can be no assurance as to whether or to what extent reimbursement will be available for any drug we commercialize. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approvals. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a doctor. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we have developed.

RISK FACTORS

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the indications and purposes for which the drug candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. 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, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may be subject to change. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for drugs with lower cost that have been covered in reimbursement policies, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by governmental healthcare programs or private payers and by any future lift or relaxation of laws and regulations that presently restrict imports of drugs from countries where they may be sold at lower prices than in the jurisdictions in which we operate or have a presence. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, financial condition, results of operations and prospects.

If safety, efficacy, or other issues arise with any medical product that is used in combination with our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our drug candidates for use as combination therapies. Combination therapy development carries a higher risk of failure compared to single agent development due to greater risk of combined drug toxicity as well as lower efficacy due to drug-drug interactions as well as toxicity limitations on efficacy. The development risks of failure are even higher if both agents are investigational. There are additional regulatory requirements for combination development to ensure patient safety during development, including the requirement for separate combination IND review and the trial designs which are also more complex and require close monitoring. If the NMPA, the FDA or another comparable regulatory agency revokes its approval of any pharmaceutical products or therapy we intend to use in combination with our drug candidates, we will be forced to terminate or re-design the clinical trials, experience significant regulatory delays, or will not be able to market our drug candidates in combination with such revoked pharmaceutical products or therapies. If safety or efficacy issues arise with these or other therapies that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the relevant clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline, or at all.

RISK FACTORS

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

The illegal import of similar or 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 plan to commercialize our drug candidates. 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 drugs 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 pharmaceutical products distributed or sold in our target markets may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their usage or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The regulatory control and law enforcement system in relation to the counterfeit pharmaceutical products, 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 in a timely manner, or at all. 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.

Counterfeit pharmaceutical products are unlikely to meet our or our collaboration partners’ rigorous manufacturing and testing standards and may even cause health damage to patients. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaboration partners’ brand name(s). In addition, theft of inventory at warehouses, plants or while in-transit, which is not properly stored and which is sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

RISK FACTORS

Lack of third-party combination drugs may materially and adversely affect demand for our drugs.

Our drug candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. We may also use third-party drugs in our development and clinical trials as controls for our studies. For example, we are currently conducting a Phase II clinical trial to evaluate the efficacy of our Core Product, M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) in MA patients in China. We also commenced a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China in February 2023 and a Phase Ib/II clinical trial of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China in March 2023. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. We generally have no influence over the availability and pricing of such drugs. If other pharmaceutical companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business, financial condition, results of operations and prospects.

The market opportunities for drug candidates for certain indications may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The field of cancer treatment has advanced rapidly in recent decades, progressing from surgery and radiotherapy, to chemotherapy and, more recently, to targeted drugs and immune-oncology therapies including cell therapies. Medication treatment with chemotherapy, targeted drugs and immune-oncology therapies can be characterized as first-line, second-line or third-line based on the timing of the treatment. First-line treatment or therapy simply refers to the initial, or first treatment recommended for the cancer, which, for most people, is expected to provide the best results with fewest side effects. In contrast, second-line treatments are used when the first-line treatment failed, or if the first-line worked initially and then the cancer progressed. Third-line treatment may be adopted if previous treatments failed.

For certain indications with well-established standard of care therapies, we may initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. For drugs that prove to be sufficiently beneficial, we may subsequently seek approval as an early-line therapy for these indications, but there is no guarantee that our drug candidates would be approved for early-line therapy. Our projections of the number of patients in a position to receive a later stage therapy and those who can potentially benefit from treatment with our drug candidates as a second- or first-line of therapy, are based on our estimates and may be inaccurate.

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Further, new studies may change the estimated incidences or prevalence of these cancers. The potentially addressable patient population for our drug candidates may turn out to be limited and lower than expected, or may not be amenable to treatment with our drug candidates. Our business may suffer if the market opportunities for our drug candidates are smaller than we anticipate, or the regulatory approvals we obtain for our drugs are based on a narrower definition of the patient population. Even if we obtain significant market shares for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including the use as an early-line therapy.

Guidelines, recommendations and studies published by various organizations could disfavor our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or indirectly relative to our competitive drug candidates, could result in current or potential decreased use of, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third-parties’ guidelines, recommendations or studies.

We may face difficulties in leveraging the clinical results of our drug candidates in China for late-stage clinical development in other jurisdictions.

There have been recent examples of the FDA declining to approve China-tested drugs mainly based on the clinical data generated in China, including sintilimab, a lung cancer drug candidate and surufatinib, a pancreatic and extra-pancreatic neuroendocrine tumor drug candidate. Sintilimab has not undergone any clinical trial in the U.S., while surufatinib has only been tested in a small-scale bridging trial in the U.S. Neither drug has been evaluated in pivotal clinical trials involving diverse populations in the U.S., nor have their pivotal clinical trial protocols been reviewed or approved by the FDA. After completing the Phase II clinical trial of M701 and the Phase Ib/II clinical trials of Y101D in China, we plan to leverage the clinical results generated in China to support the late-stage clinical development in the U.S. We plan to collaborate with overseas partners to confirm the design of late-stage clinical trials with FDA and conduct such clinical trials in the U.S., which will enable us to obtain efficacy data encompassing multiple ethnicities and form the basis for us to obtain regulatory approvals to commercialize M701 in the U.S. and some other overseas markets. However, we cannot guarantee that the FDA will accept our clinical results generated in China to support pivotal clinical trials in the U.S., and we may face difficulties and incur additional costs thereof.

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Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict post-approval activities and affect our ability to sell profitably any drug candidates for which we obtain marketing approval.

The United States Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”), is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA, the following may be of importance to our drug candidates:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers’ Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act’s pharmaceutical pricing program;
- new requirements to report to Centers for Medicare & Medicaid Services financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report to the FDA drug samples that manufacturers and distributors provide to physicians; and

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- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, on our drug candidates may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

We have limited experience in manufacturing therapeutic biologic products, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

As of the Latest Practicable Date, all of our drug candidates were in the research and development stage, and we mainly produce drugs that are used for pre-clinical studies and clinical trials. For details, please refer to the paragraphs headed “Business – Our R&D Platform – Chemistry, Manufacturing, and Controls (CMC)” in this document. We have limited experience in large-scale manufacturing of our drug candidates.

We rely on CMOs/CDMOs as well as our inhouse manufacturing capability to support the supply of drug candidates to meet our clinical and pre-clinical demands. We expect to engage third-party CMOs/CDMOs to manufacture certain of our products after they are commercialized, such as M701 and Y101D. We also plan to establish new production lines to meet the manufacturing demands for pivotal clinical trials and commercial production of Y150 and Y332. As of the Latest Practicable Date, our manufacturing center consisted of 28 members with extensive experience in CMC and manufacturing of BsAbs led by Dr. Yang Bin who has over ten years of experience in CMC processes management and drug development. However, we have seven drug candidates under clinical development and the process development and scale up of sophisticated biologics such as BsAbs are resource-intensive and time-consuming. We cannot guarantee that we will not encounter a shortage of manufacturing professionals or that our CMC technology will be able to support the production of complex BsAbs. If our in-house capacity fails to meet our clinical manufacturing needs or we are unable to engage suitable CMOs/CDMOs in a timely manner, our clinical trials may be significantly delayed, and the commercialization progress of our drug candidates could be severely impacted.

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If we are unable to identify an appropriate production site or a suitable partner to develop the manufacturing infrastructure, or fail to do so in a timely manner, it may lead to significant delays in the manufacturing of our drug candidates after we have obtained regulatory and marketing approvals. Investments in constructing or leasing new biologics manufacturing facilities which are in compliance with GMP regulations may result in significant cost for us and in turn would have a material adverse effect on our commercialization plans. We may also fail to attract and retain personnel with the requisite skills and experience for drug manufacturing.

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of drug candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and jeopardize our ability to commence product sales and generate revenue.

We may also encounter problems with achieving adequate or clinical-grade products that meet the standards or specifications of the NMPA, the FDA, or other comparable regulatory agencies, and maintaining consistent and acceptable production costs. We may experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our drugs for commercial sales. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

In addition, the quality of our products, including drug candidates manufactured by us for research and development purposes and drugs manufactured by us for commercial use, 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. 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. We are, however, working on improving our documentation procedures for quality control and quality assurance activities. 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.

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The manufacturing of therapeutic biologics products is highly complex and if we encounter problems in manufacturing our products, our business could be materially and adversely affected.

The manufacturing of therapeutic biologics products is highly complex and we have limited experience in commercial manufacturing. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. We face additional manufacturing risks in relation to the CMOs that we may engage from time to time. For details, please refer to the paragraphs headed “– Risks Relating to Our Reliance on Third Parties – We currently rely on third parties to manufacture a portion of our drug candidates for clinical development, and we may rely on third parties to manufacture our drug candidates for commercial sales in the future. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices” in this section.

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Any disruption of our current facilities or in the development of new facilities, could reduce or restrict our production capacity or our ability to develop or sell products, which could have a material adverse effect on our business, financial condition and results of operations.

We currently manufacture certain of our existing drug candidates for research and development purposes in Wuhan, China. We also engage third-party CMOs/CDMOs for the manufacturing of a portion of our drug candidates for preclinical studies and clinical trials. Our manufacturing capacity of our drug candidates may be limited, which would delay or limit our development and commercialization activities and our opportunities for growth.

Our manufacturing facilities are required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, the FDA, or other comparable regulatory authorities to ensure compliance with GMP regulations. Further, we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot guarantee that we will be able to adequately follow and document our adherence to such GMP regulations or other regulatory requirements. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or their commercialization, if approved. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

In addition, to obtain the FDA approval for our products in the United States, we would need to undergo strict pre-approval inspections of our manufacturing facilities. Historically, manufacturing facilities in China have had difficulty meeting the FDA standards. When inspecting our manufacturing facilities, the FDA may cite GMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the FDA will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction, and may note further deficiencies during re-inspection.

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Any interruption in manufacturing operations at our facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including equipment malfunctions or failures, technology malfunctions, work stoppages, damage to or destruction of either facility due to natural disasters or other unanticipated catastrophic events, water shortages or fire, regional power shortages, product tampering or terrorist activities. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and results of operation.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any of our future approved drug candidates manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially and adversely affect our business, financial condition, results of operations and prospects.

If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business and financial condition would be materially and adversely affected.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand of our drug candidates, if approved, we will need to substantially increase, or scale up, the production process. If the scale up is delayed, the cost of this scale up is not economically feasible for us, or we cannot find a third-party supplier, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

In anticipation of the commercialization of our drug candidates and market demand of our drug candidates, if approved, we aim to expand our manufacturing capacity. However, the timing and success of our capacity expansion are subject to significant uncertainty. Moreover, such plan is capital intensive and requires significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

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Furthermore, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence the operation. During the construction and ramp-up period, there may be significant changes in the biopharmaceutical industry, including, among others, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our manufacturing facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;
- construction cost overruns, which may require diverting resources and management’s attention from other projects; and
- difficulty in finding sufficient numbers of trained and qualified staff.

The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the selected markets in the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize drug candidates and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially and adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technologies that we consider commercially important by filing patent applications in China, the United States and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. A portion of our patent portfolio currently comprises pending patent applications that have not yet been issued as granted patents. For further information on our patent portfolio, please refer to the paragraphs headed “Business – Intellectual Property” in this document. Whether we can obtain the approval for each pending application is subject to the examination opinions from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications. If we or our collaboration partners are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our

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competitors could develop and commercialize drugs and technologies similar or identical to ours, and our ability to successfully commercialize our drugs and technologies may be harmed, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. If we are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed. In addition, the requirements for patentability differ in certain jurisdictions. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Patent applications may not be granted, and the granted patents may be invalidated for a number of reasons, including known or unknown prior art, deficiencies in the patent application, the lack of novelty of the underlying invention or technology or failure to comply with the confidentiality examination requirement. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Any of these reasons may delay or interfere with our commercialization plans in China and globally. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaboration partners, outside scientific collaboration partners, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in China, the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. An adverse determination in any proceeding challenging our patent rights 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

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candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world, including in the PRC.

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries across the world could be prohibitively expensive. Competitors may use our technologies in jurisdictions in which we have not obtained patent protection to develop their own drug candidates and may export otherwise infringing drug candidates to territories, including the PRC, where we have patent protection, given that the levels of law enforcement vary across jurisdictions. These drug candidates may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions, including the PRC, do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in registering, protecting and defending such rights in the relevant jurisdictions, including the PRC. Furthermore, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, there can be no assurance that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may expect to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have a material adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from

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effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Even if we are able to obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially and adversely affected.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for invention in the PRC and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the United States. Even if we successfully obtain patent protection for a drug candidate, such drug candidate may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office; thus, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant drug candidate exclusively, which would have a material adverse effect on any potential sales of that drug candidate. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates. For the expiration dates of our issued patents for our drug candidates, please refer to the paragraphs headed “Business – Intellectual Property” in this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing drugs and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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Our owned patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our collaboration partners are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, which could materially and adversely impact our business.

We or our collaboration partners may be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned patents or other intellectual property. If we or our collaboration partners are unsuccessful in any interference proceedings or other priority, inventorship or validity disputes to which we or they are subject, we may lose valuable intellectual property rights, such as loss of one or more patents or exclusive ownership, or our patent claims’ being narrowed, invalidated, or held unenforceable. As a result, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes, in order to continue the development, manufacture and commercialization of one or more of our drug candidates. However, such licenses may not be available on commercially reasonable terms or at all or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture, and commercialization of one or more of our drug candidates. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

We may also engage third-party contractors, including CROs, to assist us with the research and development of our drug candidates. There can be no assurance that such contractors will not transfer the drug candidates to other third parties without our permission. Such unauthorized transfer may also result in the loss or restriction of our intellectual property rights and therefore limit our ability to develop, manufacture and commercialize the drug candidates.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance with those requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, the United States Patent and Trademark Office (the “USPTO”) and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and other similar governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. 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 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 might be able to enter the market, which would have a material adverse effect on our business.

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The absence of patent linkage and patent term extension for NMPA-approved pharmaceutical products could increase the risk of early generic competition for our products in China.

In the United States, the Federal Food Drug and Cosmetic Act, as amended by the law generally referred to as “Hatch-Waxman”, provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we fail to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and thus our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the United States to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

RISK FACTORS

The PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the owner of the patent for an innovative new drug that has been granted the marketing authorization in China to submit applications for a patent term extension of up to a maximum length of five years, in order to compensate the time required for the regulatory approval for the commercialization of such innovative new drug; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Furthermore, the PRC government entered into the Economic and Trade Agreement Between the Government of the People’s Republic of China and the Government of the United States of America (中華人民共和國政府和美利堅合眾國政府經濟貿易協議) with the U.S. government in January 2020 which provides that the owner of the patent for an innovative new drug that has been granted the marketing authorization in China is entitled to request a patent term extension of up to five years; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years from the date of marketing approval in China. If we are unable to obtain patent term extension, or the term of any such extension is less than that we request, our competitors or other third parties may obtain approval of competing products following our patent expiration. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property and impair the intellectual property protection of our drug candidates.

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the United States or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In China, the recent amendment to the PRC Patent Law, amended in October 2020 and implemented in June 2021, introduced patent term compensation mechanism for eligible invention patents related to new drugs, but lacks operational details. The patents owned by third parties may be extended, which may in turn affect our ability to commercialize our drug candidates (if approved) without facing infringement risks. According to the PRC Patent Law, in order to compensate for the time used for the review and approval of new drugs for marketing, the patent administration department of the State Council shall, at the request of the patentee, provide patent term compensation for invention patents of new drugs approved for marketing in China. The patent term compensation may not exceed five years, and the total effective term of the patent after the new drug approved for marketing shall not exceed 14 years. If we are required to delay commercialization for an extended period of time, technological advances may develop and new drugs may be launched, which may in turn render our drug candidates non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

RISK FACTORS

Under the America Invents Act, the AIA, enacted in 2011, the United States moved to first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties’ intellectual property rights may not always be successful. Defending ourselves against third parties’ intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team’s attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor, as whether a drug candidate or technology infringes on third parties’ intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge a third-party intellectual property right may be high. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing our drug candidates, or at least delay the development or commercialization process. Even if the litigations or other proceedings are resolved in our favor, our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name.

RISK FACTORS

Granted patents covering one or more of our major drug candidates or technologies could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, the CNIPA or the applicable foreign counterpart, or made a misleading statement, during prosecution. Even if we conduct our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a drug candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activities and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the CNIPA, the USPTO or comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially and adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially and adversely affected.

RISK FACTORS

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Intellectual property rights do not necessarily protect us from all potential threats.

The degree of protection afforded by our intellectual property rights is essentially uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The limitations of currently available intellectual property protection regimes include that:

- others may be able to make products that are similar to any of our drug candidates or utilize similar or alternative technology that are not covered by the claims of the patents that we own or have exclusively licensed now or in the future;
- we or our current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;
- we or our current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- patents that may be issued from our pending patent applications may not provide us with any competitive advantages, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

RISK FACTORS

- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sales of the related product, the commercial value of our patents may be limited;
- the proprietary technologies on which we rely may not be patentable;
- the patents of others may materially and adversely affect our business; and
- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patents and pending patent applications, we rely on our trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaboration partners, outside scientific collaboration partners, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them.

However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

RISK FACTORS

Furthermore, our employees, consultants and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we, our employees, consultants and advisors, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

We may be unsuccessful in executing the agreements assigning intellectual property to us with our employees, consultants and contractors who in fact develop intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

RISK FACTORS

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our drug candidates, such as those who help us conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have worked with and plan to continue to work with third-party CROs, including SMOs, to monitor and manage data for our ongoing pre-clinical and clinical programs. We work with these parties to execute our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA, the FDA, and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA, or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms or in a timely manner. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our 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. If our CROs err in their experimental operations, the development projects of our drug candidates may be delayed or adversely affected. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. 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 effect on our business.

RISK FACTORS

Our future revenues are dependent on our ability to work effectively with collaboration partners to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaboration partners will be critical to successfully bringing drug candidates to market and commercializing them. We rely on collaboration partners in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaboration partners; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaboration partners and if any of our collaboration partners breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

We depend on a stable and adequate supply of quality materials and research and development 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 a substantial amount of raw materials as well as equipment and other materials needed for research and development and manufacturing purposes, and are therefore exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply certain materials. We expect to continue to rely on third parties to supply such materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. For details, please refer to the paragraphs headed “Business – Raw Materials and Suppliers” in this document.

There is a risk that, if supplies are interrupted, we may not be able to find alternative supplies in a timely and commercially reasonable manner, or at all, and it would materially harm our business. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of marketing approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any 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 cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the risk of increased costs, which we may not be able to pass on to customers and, as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our future drug 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.

RISK FACTORS

Additionally, our suppliers may also fail to maintain adequate quality of the services, materials and equipment we need. We cannot assure you that we will be able to identify all of the quality issues. Suboptimal or even deficient supplies of services, materials and equipment may hinder the research and development of our drug candidates, subject us to product liability claims or otherwise have a material adverse effect on our operations.

In addition, we cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Their failure to do so may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material adverse effect on our business, financial condition and results of operations.

We have collaborated with third parties in the development of drug candidates, and may seek collaboration opportunities and strategic alliances or enter into licensing arrangements in the future, but we may not realize the benefits of such collaboration, alliances or licensing arrangements.

Historically we have entered into collaboration arrangements with third parties in relation to the development of our drug candidates. For details, please refer to the paragraphs headed “Business – Collaboration Agreements” in this document. We may in the future seek and form additional strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of such relationships may require us to incur non-recurring and other charges, increase our short- and long-term capital expenditures, issue securities that dilute our existing shareholders, or divert the attention of our management from our normal course of business. Moreover, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. 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 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 a third party for the development and commercialization of a drug candidate, we may relinquish some or all of the control over the future success of that drug candidate to the third party. 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 in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

RISK FACTORS

Collaborations involving our drug candidates are subject to a number of risks, which may include but are not limited to the following:

- our collaboration partners have significant discretion in determining the efforts and resources that they will allocate to such collaborations or strategic alliances;
- our collaboration partners may not pursue development and commercialization of drug candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- our collaboration partners may delay their drug development plan, including clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- our collaboration partners could independently develop, or develop with other third parties, drugs that compete directly or indirectly with our drug candidates;
- our collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaboration partners may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and our collaboration partners 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;
- collaborations may be terminated if we or our collaboration partners fail to comply with our or their obligations in the collaboration agreements;
- termination of collaborations may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidates;
- our collaboration partners may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- our collaboration partners with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drug candidates.

RISK FACTORS

We cannot be certain that, following a strategic transaction, we will be able to generate the target level of revenue or profit that can justify such a transaction. If we are unable to reach agreements with suitable collaboration partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development 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, results of operations and prospects.

We currently rely on third parties to manufacture a portion of our drug candidates for clinical development, and we may rely on third parties to manufacture our drug candidates for commercial sales in the future. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.

During the Track Record Period, we outsourced certain manufacturing activities of our drug candidates to selected CMOs/CDMOs. Such outsourcing occurs when our own manufacturing capacity is insufficient and when we seek to reduce regulatory compliance costs. Going forward, we plan to continue to work with industry-leading and reputable CMOs/CDMOs. Reliance on third-party CMOs/CDMOs would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or in a timely manner, or at all, because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and GMP-compliance inspections by the NMPA, the FDA or other comparable regulatory authorities;
- our CMOs/CDMOs might be unable to timely produce the drug candidates or not in the quantity and quality required to meet our needs for clinical trials and commercial sales, if any;
- manufacturers are subject to ongoing periodic inspections by the NMPA or the FDA, or other comparable regulatory authorities, as applicable, to ensure strict compliance with GMP and other government regulations and we do not have control over CMOs/CDMOs’ compliance with these regulations and requirements;

RISK FACTORS

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers 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;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our CMOs/CDMOs and critical raw materials suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, or result in higher costs or adversely impact the commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm, and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

Manufacturers of biological products often encounter problems including logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced laws and regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities of our CMOs/CDMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future in relation with our CMOs/CDMOs. Additionally, our CMOs/CDMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved drug candidates for commercial sales and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

RISK FACTORS

RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATIONS

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with existing or future regulations and industry standards or any adverse actions by drug approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.

All jurisdictions in which we intend to develop and commercialize our drug candidates and conduct other pharmaceutical-industry activities regulate these activities in great depth and detail. We adopt a global development strategy and intend to focus our activities in the major markets including China and the United States. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development and approval, manufacturing, marketing, sales and distribution of pharmaceutical products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions. Our or our CROs’ failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations.

We are also subject to the uncertainties and changes in the laws and regulations in all jurisdictions in which we intend to develop and commercialize our drug candidates and conduct other pharmaceutical-industry activities. For example, on September 12, 2022, the President of the United States issued “Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy” (the “Executive Order”), launching a national biotechnology and biomanufacturing initiative in the United States. This initiative will be comprised of various efforts by the U.S. government, including investments, programs and partnerships to advance research and development in biotechnology and biomanufacturing, as well as efforts to secure and protect the U.S. bioeconomy. The Executive Order may lead to potential changes to U.S. policies affecting the biotechnology and biomanufacturing industries. Substantially all of our operations and all of our clinical trials are conducted in China. We plan to conduct clinical trials for certain drug candidates and explore development and/or commercialization opportunities in the United States in the future. We therefore expect that the Executive Order will have no immediate impact on our research and development activities in the United States. However, it is unknown at this time whether and what specific policies and actions will be adopted by the U.S. government. If the U.S. government were to adopt any policies that adversely impact foreign companies conducting research and development activities in the United States, our business, financial condition and results of operations could be adversely affected.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the drug

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development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Failure to comply with these regulations could therefore materially and adversely affect our business, financial condition, results of operations and prospects.

Moreover, the regulatory framework regarding the pharmaceutical industry is continuing to change and evolve, and we cannot guarantee that changes to the laws and regulations with regard to pharmaceutical industry in jurisdictions where we operate would not adversely affect our business and prospects. Any such changes or amendments may result in increased compliance difficulty and costs or cause delays in, or prevent the successful development or commercialization of, our drug candidates and reduce the current benefits we believe are available to us from developing and manufacturing our drug candidates. Changes in government regulations or in practices relating to the pharmaceutical industry such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be substantially harmed.

We are subject to risks associated with obtaining regulatory approvals. Difficulties and failures in doing so may expose us to various harms. Significant time, effort and expense are required to bring our drug candidates to market in compliance with the regulatory process, and we cannot assure you that any of our drug candidates will be approved for sale. The time required to obtain approvals from the NMPA, the FDA, and other comparable regulatory authorities is unpredictable but typically takes 10 to 15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, regulations, approval policies and requirements for clinical data may change during the clinical development process of a drug candidate and may vary among jurisdictions. It is not uncommon that the NMPA, the FDA or a comparable regulatory authority may require more information, including additional analysis, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may increase our costs, prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. We cannot assure you that we will be able to meet regulatory

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requirements of different jurisdictions or that our drug candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

Our drug candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and potent for its proposed indications or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure to demonstrate that the clinical and other benefits of a drug candidate outweigh its safety risks;
- failure of clinical trial results to meet the level of statistical and medical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- insufficiency of data from clinical trials of our drug candidates to support the filing of the submission or to obtain regulatory approval;
- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial resulting in failure to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities and a potential invalidation of our research data;
- failure of our clinical trial process to keep abreast with any scientific or technological advancements required by regulations or approval policies; and
- findings by the NMPA, the FDA or other comparable regulatory authorities of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies.

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Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA, and other comparable regulatory authorities may also change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, on November 19, 2021, the CDE issued the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研髮指導原則》), or the Clinical Guidelines, for anti-tumor drugs, which aims to promote the patient-oriented research and development concept throughout the clinical trial design. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Moreover, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries.

We may experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates. Any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates, and may cause reputational damage.

We cannot assure you that we can satisfy all regulatory requirements to obtain regulatory approvals in a timely manner, or at all, or to obtain regulatory approvals with an ideal scope of indications, which may have an adverse impact on our reputation and the commercial prospects of our drug candidates, and eventually may harm our business, financial condition and prospects significantly.

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Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or a significant change in our clinical protocol or our development plan and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or could result in limitations or withdrawal following approvals.

If results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

Adverse events caused by our drug candidates, including when used in combination therapy, which may involve unique adverse events that could be exacerbated compared with adverse events from monotherapies, and off-label use of our drug candidates could potentially cause significant negative consequences for our Company, including:

- regulatory authorities could delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of the drug candidates;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug candidate;
- we may be required to develop a risk evaluation and mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation and mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to subjects or patients;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;

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- the costs of clinical trials of our drug candidates may be substantially higher than anticipated; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could materially and adversely affect our business, financial condition, results of operations and prospects.

The regulatory pathway for COVID-19 vaccines is highly dynamic and continues to evolve and may result in unexpected or unforeseen challenges.

The speed at which all parties are acting to develop and test many vaccines against the SARS-CoV-2 virus is unusual, and evolving or changing plans or priorities within the NMPA, the FDA, the WHO and other regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for Y2019.

Results from clinical testing may also raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. For example, The NMPA and the WHO prioritize the regulatory administration on COVID-19 vaccines, while emphasizing on various regulatory requirements on pre-clinical studies and clinical trials. We cannot be certain that, as the regulatory pathway continues to evolve, we will be able to complete future clinical trials for Y2019 in accordance with the applicable guidance and regulations then in effect.

A failure to complete a clinical trial in accordance with guidance and regulations then in effect could impair our ability to obtain approval for Y2019, which may adversely affect our operating results, reputation and ability to raise capital and enter into or maintain collaborations to advance our other product candidates.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We routinely receive, collect, generate, store, process, transmit and maintain medical data, treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. 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. Failure to comply with any of

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these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients’ privacy, privacy leakage incidents might not be avoided due to hacking activities, human error, employee misconduct or negligence or system breakdown.

In addition, our clinical trials also frequently involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure.

Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Noncompliance could result in 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 fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

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We are subject to registration, review and other requirements of the regulatory authorities for cross-border sales or licensing of technology as well as operations related to genetics and data safety.

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (《技術進出口管理條例》) promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (《技術進出口合同登記管理辦法》), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology.

We may in the future enter into agreements with CROs in the United States for their technical support to assist us with the development of individual drug candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are required to be registered with applicable PRC governmental authorities. We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology (科學技術部人類遺傳資源管理辦公室) who will conduct genetics and data safety review. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 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》), or the Scientific Data Measures, which provide 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 or individual privacy 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. If and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, 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. 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 condition 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.

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Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, storage, distribution, adverse event reporting, advertising, promotion, sampling, recordkeeping and post-marketing studies for the drug will be subject to extensive and ongoing or additional regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any CMC, variations, continued compliance with GMPs, cGMPs, GCPs, good storage practices (GSPs) and good vigilance practices (GVPs) and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved by the NMPA, the FDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug candidates, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA, the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the NMPA, the FDA or comparable regulatory authorities to accept any of our other IND approvals, NDAs or BLAs;
- suspension or revocation of existing drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

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The NMPA, the FDA and comparable regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, the FDA and other comparable regulatory authorities 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. Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be directly or indirectly subject to applicable anti-kickback, anti-bribery, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and the United States. These laws may impact, among other things, our proposed sales and marketing programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with governments.

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope than others and may apply to healthcare services reimbursed by any source, which may include not only governmental payers, but also private insurers, and if we fail to comply with any such requirement, we could be subject to penalties.

There is no definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

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In addition, we are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Moreover, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act (the “FCPA”). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. There is no assurance that policies or procedures to ensure the compliance with anti-bribery laws will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

RISKS RELATING TO OUR OPERATIONS

The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and sales personnel could adversely affect our business.

Our commercial success depends significantly on the continued service of our senior management. For more details of our senior management, please refer to the section headed “Directors, Supervisors and Senior Management” in this document. The loss of any of our senior management could have a material adverse effect on our business and operations. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time.

We could experience difficulties attracting and retaining qualified employees in the future. Competition for qualified employees in the pharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced senior management or key scientific and clinical personnel in the future. The departure of one or more of our senior management or key scientific and clinical personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our drug development progress and have a material adverse effect on our business and results of operations.

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Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biopharmaceutical companies for similar personnel. 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 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, results of operations, cash flows and prospects.

As we have significantly increased the size and capabilities of our organization since our inception, we may experience difficulties in managing our growth.

We are a rapidly growing company working on a rich and expanding pipeline of drug candidates. Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As our development and commercialization plans and strategies evolve, we must hire a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant additional responsibilities on our management, including but not limited to:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technologies in the highly competitive pharmaceutical industry;
- managing our relationships with third parties, including suppliers and collaboration partners;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially and adversely affect our business, financial condition, results of operations and prospects.

We may engage in acquisitions or strategic partnerships, which may increase our capital requirements, cause dilution for our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions, joint ventures and strategic partnerships, including licensing or acquiring drug products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- the loss of key employees and personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

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We may not be able to identify attractive targets, and we have limited experience in acquisitions. In addition, we may not be able to successfully acquire the targets identified despite spending a significant amount of time and resources on pursuing such acquisition. Furthermore, integration of an acquired company, its intellectual property or technology into our own operations is a complex, time-consuming and expensive process. The successful integration of an acquisition may require, among other things, that we integrate and retain key management, sales and other personnel, integrate the acquired technologies or services from both an engineering and a sales and marketing perspective, integrate and support preexisting supplier, distribution and customer relationships, coordinate research and development efforts, and consolidate duplicate facilities and functions. The geographic distance between companies, the complexity of the technologies and operations being integrated, and the disparate corporate cultures being combined may increase the difficulties of integrating an acquired company or technology. In addition, it is common in our industry for competitors to attract customers and recruit key employees away from companies during the integration phase of an acquisition. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

We face risks related to health epidemics and other outbreaks of contagious diseases, including the COVID-19 outbreak.

Since the end of December 2019, the outbreak of a novel strain of coronavirus named COVID-19 has materially and adversely affected the global economy. Many countries and regions, including China, had been affected by the COVID-19 outbreak and, in response, had imposed certain lockdown measures, closure of workplaces and restrictions on mobility and travel to contain the spread of the virus. Due to the COVID-19 outbreak, we may experience one or more of the following disruptions to drug development efforts and business operations:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in logistics that may affect the transport of clinical trial materials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, patient treatment and efficacy evaluation;

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- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- temporary closure of certain office facilities and adopting remote working where possible;
- restriction of employee travels, which may adversely affect the sales and marketing efforts;
- disruption to the manufacturing activities;
- disruption to the supplies of our drug candidates in clinical trials; and
- delays in or temporary suspension of the construction of our manufacturing facilities.

These disruptions could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section. For details, please refer to the paragraphs headed “Financial Information – Impact of the COVID-19 Outbreak” in this document.

Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 cases in several parts of China due to the spread of the Omicron variant. The COVID-19 related restrictive measures adopted by the Chinese government were lifted in various regions in China in December 2022. However, the exacerbation, continuance or resurgence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in China and other affected countries. We cannot predict when the COVID-19 outbreak and resurgences will become completely under control and we cannot guarantee that the COVID-19 outbreak and resurgences will not worsen. The extent to which the COVID-19 outbreak and resurgences may impact our business in the future will depend on future developments, which are highly uncertain and unpredictable, such as the duration of the outbreak, the effectiveness of vaccines and vaccination rates in China and overseas, and other measures to contain the outbreak and its impact in countries and regions where we operate. Having considered that the past occurrences of epidemics, depending on their scale, have caused different degrees of damage to the global and China’s economy, the COVID-19 outbreak and any other public health crisis in China or overseas, especially in the cities where we have presence, may result in material disruptions to our operations, which in turn may materially and adversely affect our business, financial condition and results of operations.

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We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

We primarily operate and currently conduct all our clinical trials in China. As we may further our development efforts for our drug candidates in the United States in the future, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country’s or region’s political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management’s attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- inadequate intellectual property protection in certain jurisdictions;
- 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;
- the enforcement of anti-corruption and anti-bribery laws against us;
- trade protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, and greater difficulty in accounts receivable collection;
- non-compliance with tax, employment, immigration and labor laws;

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- the effects of applicable local tax regimes and potentially adverse tax consequences;
- significant adverse changes in local currency exchange rates; 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.

Furthermore, global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors, including extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

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. Litigation to which we subsequently become a party might result in substantial costs and divert management’s attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings that may initially not appear to be of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. We believe that we have maintained adequate insurance to cover our key liabilities arising from such proceedings. For more details of our insurance, please refer to the paragraphs headed “Business – Insurance” in this document. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

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

We maintain insurance policies that are required under the PRC laws and regulations and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover adverse events in our clinical trials. We also maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations. However, our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

We benefit from certain preferential tax treatments and government grants, and the expiration of or changes to these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

During the Track Record Period, we enjoyed preferential tax treatment. For example, pursuant to the Notice of Raising the Proportion of Weighted Pre-tax Deduction of Research and Development Expenses (關於提高研究開發費用稅前加計扣除比例的通知) issued by the Ministry of Finance, the State Administration of Taxation and the Ministry of Science and Technology on September 20, 2018, we enjoyed super deduction of 175% on qualifying research and development expenses during the Track Record Period. We cannot assure you that these preferential tax treatments will continue to be available to us in the future, or that these preferential tax treatments will not be changed, as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected. Moreover, we recorded government grants of RMB12.1 million and RMB2.3 million for the years ended December 31, 2021 and 2022, respectively. These government grants were generally in support of our research and development activities, including subsidies to encourage R&D activities, reimbursement for R&D expenses and subsidies for talent recruitment.

The government authorities have the sole discretion to determine the timing, amount and criteria of such financial incentives and may review and assess such criteria and conditions from time to time. One of the government subsidies we received during the Track Record Period is subject to a condition that we should complete the R&D projects for Y2019. Our compliance with such condition is under the assessment of the relevant government authority. Although we do not expect any material impediment to get approved in such assessment, we generally do not have the ability to influence government authorities in making these decisions. Government authorities may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including achievement of technological innovation, recruitment and retention of talent, compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, otherwise we may be deprived of all or part of the incentives. For instance, we received a government subsidy for construction of R&D facilities, with a condition that the construction should be completed and approved by the relevant PRC government authority before December 31, 2016. As of the Latest Practicable Date, we had not

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fulfilled such condition. As a result, this subsidy is repayable to the relevant PRC government authority on demand. For more details, please refer to the paragraphs headed “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Positions – Trade and Other Payables” in this document.

Except as disclosed above, during the Track Record and up to the Latest Practicable Date, we had complied with all the conditions required to receive government grants. However, we cannot assure you that we will continue to receive government grants, or preferential tax treatments at the same level or at all, in which case our business, financial condition and result of operations may be adversely affected.

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

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, sales and marketing, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. Increasing market competition may cause market demand and competition for qualified employees to intensify. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially and adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused. Any of the foregoing changes could have a material adverse effect on our business, results of operations and prospects.

If we or our CROs fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health, and safety laws and regulations in China and the United States, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of discovery, testing, development and manufacturing of our drug candidates. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. We may also be forced to close or suspend operations at certain of our affected facilities temporarily or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material adverse impact on our business, financial condition, results of operations and prospects.

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We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our drug candidate R&D program efforts. Moreover, there is increasing stakeholder pressure on companies to diligence environmental, social, and governance matters in the supply chain. Negative publicity regarding production methods, alleged practices or workplace or related conditions of any of our suppliers, CROs or other third parties who perform services for us could adversely affect our reputation and force us to locate alternatives, which could increase our costs and result in delayed supply of components for, and manufacturing of, our drug candidates, or other disruptions to our operations.

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.

Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees, principal investigators, consultants and commercial partners.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. We may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

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If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In addition, although currently our primary operating business is in China, we are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. There is no assurance that our internal policies or procedures related to compliance with anti-bribery laws will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

Any failure to comply with applicable regulations and industry standards or obtain or renew certain approvals, various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC, the United States and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our CROs’ failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. 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. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations.

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Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

The PRC government may impose fines or other penalties on us if we fail to comply with the terms of the land grant contracts.

Under PRC laws, if we fail to develop a property project according to the terms of the land grant contract, including those relating to the designated use of the land and the time for commencement and completion of the property development, government authorities may issue a warning, impose a penalty and/or order us to forfeit the land. Specifically, under current PRC laws, if we fail to pay any outstanding land grant premium by the stipulated deadlines, we may be subject to late payment penalties or the repossession of the land by the PRC government. If we fail to commence development after one year of the commencement date stipulated in the land grant contract, the relevant PRC land bureau may issue a warning to us and impose an idle land penalty equivalent to or less than 20% of the land premium. If we fail to commence development within two years from the commencement date stipulated in the land grant contract, the relevant PRC land bureau may confiscate our land use rights without compensation, except where the delay in the development is attributable to a force majeure event or the action of the relevant government department or delay in the requisite preliminary work preceding commencement of such development. Moreover, had the development of the property commenced in accordance with the timeframe stipulated in the land grant contract, however, if such development was suspended for more than one year without government approval and falls under either of the following two situations: (i) the developed land area is less than one-third of the total land area, or (ii) the total invested capital is less than one-fourth of the total planned investment in the project, then the land may be treated as idle land and will be subject to the risk of forfeiture.

We experienced certain delays in completing the construction project on a land parcel we acquired in Wuhan, Hubei in 2012 pursuant to a land grant contract with Wuhan Municipal Bureau of Natural Resources and Planning, East Lake High-tech Development Zone Branch. For more details, please refer to the paragraphs headed “Business – Land and Properties – Land, Construction-in-Progress and Owned Properties” in this document. Except for such delays, we did not have any other previous incident failing to comply the terms of the land grant contract as of the Latest Practicable Date. We cannot assure you that our property development projects will not be subject to idle land penalties or be taken back by the government as a result of such delays, nor can we assure that we will not be imposed liquidated damages by competent PRC authorities. The occurrence of such events may have a material adverse effect on our business, results of operations and financial condition.

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Any failure to comply with the PRC regulations regarding contribution of social insurance premium or housing provident funds may subject us to fines and other legal or administrative sanctions.

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), the Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) and other applicable PRC regulations, any employer operating in China must contribute social insurance premium and housing provident funds for its employees. Any failure to open social insurance or housing provident fund registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium or housing provident funds for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium or housing provident funds within a specified period of time, and the competent authority may further impose fines or penalties. During the Track Record Period, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees. For more details, please refer to the paragraphs headed “Business – Employees – Employee Benefits” in this document. We cannot assure you that the competent authority will not require us to rectify any non-compliance by making contribution of overdue social insurance premium or housing provident funds or to pay any overdue fine or penalty related thereto.

We are subject to risks associated with leasing space.

We lease some of our offices, laboratories and facilities in China. The lessors of the leased properties may not have valid title or the legal rights to such leased properties or may not have complied with all the necessary property leasing procedures. If lessors are not entitled to lease properties to us, relevant leases might be invalidated. We may have to renegotiate with new lessors and the terms of the new leases may be less favorable to us. In addition, as our leases expire, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, six of our leases had not been filed with the governmental authorities. For more details, please refer to the paragraphs headed “Business – Land and Properties – Leases” in this document. The failure to file and obtain property leasing filing certificates for such six leases, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed. If such fines are imposed, the maximum penalty we may be required to pay would be approximately RMB70,000.

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Our internal information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our data utilizing on-site systems and outsourced vendors. Such data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information technology systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or vendors that provide information systems, networks or other services to us pose increasing risks. Despite the implementation of security measures, our internal information technology systems and those of our current and any future third-party vendors, collaboration partners, consultants, and third parties performing services for us, as well as our clinical sites and regulatory authorities, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures. In addition, the COVID-19 pandemic has intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely.

If any such material system failure, accident, or security breach were to occur and cause interruptions in our operations, it could result in a disruption of our drug candidate development and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from our current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss, or otherwise compromise our confidential or proprietary information and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our drug candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our company, our third-party vendors, and clinical sites, including personal information of our employees and, potentially, our clinical study patients, and company and vendor confidential data. In addition, third parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to data and systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

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In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. The development and maintenance of the systems, controls, and processes to prevent such events from occurring and/or identify and mitigate threats is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated.

Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with clinical sites and collaboration partners, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems, or those of third parties with which we conduct business, will be sufficient to protect us against breakdowns, service disruption, data deterioration, or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks, or insider threat attacks, which could result in financial, legal, business, or reputational harm.

Our reputation is important to our business success, and damage to our reputation may adversely affect our business.

We, our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation and commercialization. As a result, we may be required to spend significant time and incur substantial costs to respond and protect our reputation, and we cannot assure you that we will be able to do so within a reasonable period of time, or at all, in which case our business, results of operations, financial condition and prospects may be materially and adversely affected.

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RISKS RELATING TO DOING BUSINESS IN CHINA

Changes in the political and economic policies of the Chinese government may materially and adversely affect our business, financial condition, results of operations and prospects, and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in the PRC, our business, financial condition, results of operations and prospects are affected to a significant extent by economic, political, and legal developments in the PRC. The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in the PRC is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over the economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions, and providing preferential treatment to particular industries or companies. For example, the Clinical Guidelines issued by the CDE on November 19, 2021 state that the fundamental purpose of the drug market is to address the needs of patients, and emphasize that drug research and development should be based on patient needs and clinical value. The Clinical Guidelines discourage repetitive research and development of “me-too drugs” (drugs with identical mechanisms of actions) and disorderly waste. If we are unable to comply with, or are deemed to be in violation of the Clinical Guidelines’ detailed provisions and principles, our clinical development activities and overall business operations may be materially and adversely affected.

While the PRC economy has experienced significant growth in the past three decades, such growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy but may also have a negative effect on us. Our business, operating results, and financial condition could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us. In addition, the PRC government has implemented in the past certain measures to control the pace of economic growth. These measures may cause decreased economic activity, and the business environment in China could deteriorate from the perspective of domestic or international investment. Any of the foregoing would materially and adversely affect our business, financial condition, results of operations and prospects.

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There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

Substantially all of our operations are conducted in the PRC and are governed by the PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited binding precedential value. Since 1979, the PRC government has promulgated laws, rules 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, the PRC has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in the PRC or may be subject to various degrees of interpretation by the PRC regulatory agencies.

In particular, since the PRC pharmaceutical industry is experiencing ongoing reform, the laws and regulations relating to this industry may be unspecific and may be incomprehensive or inconsistent. Since these laws, rules and regulations are relatively new and often grant the relevant regulators significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. 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, and may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

The NMPA’s recent reform of the drug approval system may also face implementation challenges. The timing and full impact of such reforms are uncertain and could prevent us from commercializing our drug candidates in a timely manner. For example, the NHC issued the Administrative Measures for Clinical Use of Oncology Drugs (Trial) (抗腫瘤藥物臨床應用管理辦法(試行)), or the Administrative Measures, effective from March 1, 2021, requiring the oncology drugs, as classified into the “restricted-use” and “normal-use” categories, to be rationally used or prescribed by the medical institutions and medical practitioners. To facilitate the implementation of the Administrative Measures, in June 2021, the NHC further issued the Administrative Measurements for Rational Clinical Use of Oncology Drugs (抗腫瘤藥物臨床合理應用管理指標), or the Administrative Measurements, which specify the calculation formula for the administrative measurements used for gauging the rational use of restricted-use oncology drugs, while not setting any numeric limits on the measurements. We currently do not experience or foresee any potential material adverse impact of the Administrative Measures or the Administrative Measurements on our business operations. However, as such administrative regulations are newly released and relevant measures are generally evolving, we cannot assure you if our business operations will be adversely affected in the future.

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In addition, any administrative or court proceedings in the PRC may be protracted, resulting in substantial costs and diversion of resources and management’s attention. Since the PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition, results of operations and prospects.

The relationships between China and other countries may affect our business operations.

The U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as imposing several rounds of tariffs affecting certain products manufactured in the PRC. For example, in 2018, the United States announced three finalized tariffs that applied exclusively to products imported from China, totaling approximately US\$250 billion, and in May 2019, the United States increased the rate of certain tariffs previously levied on Chinese products from 10% to 25%. In addition, in August 2019, Former President Donald J. Trump threatened to impose additional tariffs on remaining Chinese products, totaling approximately US\$300 billion. Although on January 15, 2020, the United States and China signed an agreement on the phase one trade deal, under which both parties made certain concessions and agreed not to proceed with additional tariffs against one another, the 25% tariffs on US\$250 billion of Chinese imports are still in place. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry.

While we have not started commercialization of any of our drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or may prevent us from selling our future drug products in certain countries. If any new tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

The existing trade disputes may escalate going forward and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Trade disputes, tensions and political concerns between the PRC and the relevant foreign countries or regions may therefore adversely affect our business, financial condition, results of operations, cash flows and prospects.

RISK FACTORS

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

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of H shares by such shareholders.

According to the Individual Income Tax Law of the PRC and the Implementation Regulations for the Individual Income Tax Law of the PRC, both came into effect on January 1, 2019, the tax applicable to non-PRC resident individuals is proportionate at a rate of 20% for any dividends obtained from within China or gains on transfer of shares and shall be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the “Arrangements”) executed on August 21, 2006, the PRC Government may levy taxes on the dividends paid by PRC companies to Hong Kong residents in accordance with the PRC laws, but the levied tax (in the case the beneficial owner of the dividends are not companies directly holding at least 25% of the equity interest in the company paying the dividends) shall not exceed 10% of the total dividends.

According to the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on April 23, 2019, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; (ii) otherwise, 10% of the total amount of dividends.

Significant uncertainties remain regarding the interpretation and enforcement of applicable tax laws and regulations in the PRC by the PRC tax authorities, including whether and how income tax will be levied on non-PRC resident shareholders. Considering these uncertainties, non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

RISK FACTORS

Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your investment.

The PRC Government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to pay dividends, if any, to holders of our H Shares, or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC Government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China’s declining foreign currency reserves, the PRC Government has placed increasingly stringent restrictions on the convertibility of the Renminbi into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in China against us or our management named in the documents based on Hong Kong or other foreign laws.

We are incorporated under the laws of China, and substantially all of our assets are located in China. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all of their assets are located within the PRC. Therefore, it may be difficult for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in the PRC. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of Hong Kong Special Administrative Region 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, which was taken into effect on August 1, 2008.

RISK FACTORS

Pursuant to the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. 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 mainland court is expressly selected 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), or 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 China. The New Arrangement does not include the requirement for a choice of court agreement in writing by the parties. 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, supersede 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.

Furthermore, China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, or most other western jurisdictions or Japan. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares, and their liquidity and [REDACTED] may be volatile.

No public market currently exists for our H Shares. The [REDACTED] for our H Shares to the public will be the result of negotiations between our Company, the [REDACTED] and the [REDACTED] on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the [REDACTED] of the H Shares following the [REDACTED]. We have applied for [REDACTED] of and permission to [REDACTED] our [REDACTED] on the Stock Exchange. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for the Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED].

RISK FACTORS

The [REDACTED] and [REDACTED] of our H Shares may be volatile, which could lead to substantial losses to investors.

The [REDACTED] and [REDACTED] of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our H Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] of our H Shares may be highly volatile for specific business reasons, including but not limited to:

- the results of clinical trials of our drug candidates;
- the results of our applications for regulatory approvals of our drug candidates;
- regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters;
- fluctuations in our revenue, earnings, cash flows, investments and expenditures;
- relationships with our collaboration partners and suppliers;
- movements or activities of key personnel;
- announcements made by us or our competitors;
- acquisitions by us or our competitors;
- other actions taken by competitors;
- release or expiry of lock-up or other transfer restrictions on our H shares; and
- the general economy and other factors.

Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance.

There will be a gap of several days between [REDACTED] and [REDACTED] of our H Shares, and the [REDACTED] of our H Shares when [REDACTED] begins could be lower than the [REDACTED].

The [REDACTED] to the public of our H Shares [REDACTED] in the public market is expected to be determined on the [REDACTED]. However, the H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the [REDACTED]. As a result, investors may not be able to [REDACTED] or otherwise [REDACTED] in the H Shares during that period. Accordingly, Shareholders of our H Shares are subject to the risk that the [REDACTED] of the H Shares when [REDACTED] 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 [REDACTED] and the time [REDACTED] begins.

RISK FACTORS

Future sales or perceived sales of our H Shares in the public market by major Shareholders following the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares.

Prior to the [REDACTED], there has not been a public market for our H Shares. Future sales or perceived sales by our existing Shareholders of our H Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our H Shares. Only a limited number of the H Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our H Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] of our H Shares and our ability to raise equity capital in the future.

Raising additional capital may cause dilution to the interests of our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may finance our future cash needs through equity offerings, licensing arrangements or other collaborations, government funding arrangements, debt financings, or any combination thereof. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our H Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [REDACTED] of our H Shares to decline.

Potential investors will experience immediate and substantial dilution as a result of the [REDACTED] and will experience further dilution if we [REDACTED] additional Shares or other equity securities in the future.

Potential investors will pay a [REDACTED] per H Share in the [REDACTED] that substantially exceeds the per H Share value of our tangible assets after subtracting our total liabilities as of December 31, 2022. Therefore, [REDACTED] of our H Shares in the [REDACTED] will experience a substantial immediate dilution in [REDACTED], and our existing Shareholders will receive an increase in the [REDACTED] per Share on their Shares. As a result, if we were to distribute our net tangible assets to the Shareholders immediately following the [REDACTED], potential investors would receive less than the amount they paid for their H Shares. For more details, please refer to “Appendix II – Unaudited [REDACTED] Financial Information” to this document.

RISK FACTORS

In order to expand our business, we may consider [REDACTED] and issuing additional Shares in the future. Purchasers of our H Shares may experience dilution in the net tangible asset value per share of their H Shares if we [REDACTED] additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time. Furthermore, we may grant additional share-based compensation to eligible personnel and [REDACTED] additional Shares pursuant to share incentive schemes in the future, which would further dilute Shareholders’ interests in our Company.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on [REDACTED] of our H Shares for a return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline drug candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our H Shares as a source for any future dividend income.

The decision on whether to pay dividends will be made at the discretion of our Board. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your investment in our H Shares will likely depend entirely upon any future [REDACTED] of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the H Shares. You may not realize a return on your investment in our H Shares and you may even lose your entire investment in our H Shares.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry may not be fully reliable.

Certain facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources and for reference only, including information provided or published by government agencies, and we can not guarantee either the quality nor reliability of such source materials. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, neither we, the Sole Sponsor, the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be

RISK FACTORS

inaccurate, and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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.

You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in making your investment decision regarding our H Shares. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

<u>Name</u>	<u>Address</u>	<u>Nationality</u>

Executive Director

Dr. Zhou Pengfei	1602, Unit 2, Building 7, Phase I Xinshijie Hengda Huafu No. 10 Guanggu 1st Road Hongshan District Wuhan, Hubei Province PRC	Canadian

Non-executive Directors

Yuan Qian (袁謙)	3101, Building 2, Lanhai Park No. 88 Huaihai Road Qiaokou District Wuhan, Hubei Province PRC	Chinese

Dr. Zhou Hongfeng (周宏峰)	No. 21, No. 2 Street, Cuishan Lantianyuan Huanan Biguiyuan North Panyu Avenue South Village Town Panyu District Guangzhou, Guangdong Province PRC	Chinese

Pang Zhenhai (龐振海)	Room 203, Unit 5, Building 11 Xiyayuan No. 336 Youyi North Street Xinhua District Shijiazhuang, Hebei Province PRC	Chinese

Hui Xiwu (惠希武)	T19-1-0803, Tianhai Yutianxia Community No. 85 North Tower Road Yuhua District Shijiazhuang, Hebei Province PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Liang Qian (梁倩)	3-1-201, Xishan Garden No. 26 Yuying Road Shangzhuang Town Luquan District Shijiazhuang, Hebei Province PRC	Chinese
Dr. Liu Dan (柳丹)	25/F, Fortune Financial Center No. 5 Dong San Huan Central Road Chaoyang District Beijing PRC	Chinese
Dr. Guo Hongwei (郭宏偉)	No. 7, 16/F, Building 7 Kangleli Community Xicheng District Beijing PRC	Chinese
Xie Shouwu (謝守武)	Room 2106, Unit 2 Jindi Gelin Dongjun Community East Lake High-Tech Development Zone Wuhan, Hubei Province PRC	Chinese

Independent Non-executive Directors

Dr. Cheng Bin (程斌)	1403, Unit 2, Building 19 Tongxin Garden Qiaokou District Wuhan, Hubei Province PRC	Chinese
Dr. Dai Weiguo	Room 105, Building 26 Yanlan Xinchun No. 2 Nengyuan West Road Changping District Beijing PRC	American
Fu Lili (付黎黎)	29B, Hung Uk Clearwater Bay Hong Kong	Chinese (Hong Kong)

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Dr. Deng Yuezhen (鄧躍臻)	Room 603, Building 721 Weifang Qi Village No. 716 Weifang Road Pudong New Area Shanghai PRC	Chinese
Dr. Chen Bin (陳斌)	1306, Hongxing Coast, Xiaomeisha Yantian District Shenzhen, Guangdong Province PRC	Chinese

SUPERVISORS

Name	Address	Nationality
Sun Jumin (孫聚民)	No. 202, Building 2 Jiangxin Yingyuan Liuyang Street Qiaodong District Shijiazhuang, Hebei Province PRC	Chinese
Liu Fang (劉芳)	Room 4, 11/F, Unit 2, Building 1 Dingxiu Lianghu Shijia No. 59 Northwest Lake Road Jiangnan District Wuhan, Hubei Province PRC	Chinese
Ji Changtao (紀昌濤)	1303-1305, New World Center No. 6009 Yitian Road Futian District Shenzhen, Guangdong Province PRC	Chinese
Dr. Yi Jizu	Room 710, Unit 3, Building B1 Wuhan Vanke City Garden South (Vanke Hongjun) No. 1 Daxueyuan Road East Lake High-Tech Development Zone Wuhan, Hubei Province PRC	American
Zhang Jing (張敬)	Room 403, Unit 1, Building C Jiukun Qinnanduhui No. 139 Qinyuan Road Wuchang District Wuhan, Hubei Province PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

For further details, please refer to the section headed “Directors, Supervisors and Senior Management” in this document.

**Sole Sponsor, [REDACTED] and
[REDACTED]**

**China Securities (International)
Corporate Finance Company Limited**
18/F, Two Exchange Square
8 Connaught Place
Central
Hong Kong

[REDACTED]

Legal Advisors to the Company

As to Hong Kong law:
Cooley HK
35/F, Two Exchange Square
8 Connaught Place
Central
Hong Kong

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

As to PRC law:

Jingtian & Gongcheng

34/F, Tower 3
China Central Place
77 Jianguo Road
Chaoyang District
Beijing
PRC

As to PRC intellectual property law:

King & Wood Mallesons

18/F, East Tower, World Financial Center
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PRC

**Legal Advisors to the Sole Sponsor and
the [REDACTED]**

As to Hong Kong law:

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As to PRC law:

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Beijing
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Reporting Accountants and Auditor

Deloitte Touche Tohmatsu

Certified Public Accountants

Registered Public Interest Entity Auditor
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Admiralty
Hong Kong

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Industry Consultant

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PRC

Compliance Adviser

Gram Capital Limited

Room 1209, 12/F, Nan Fung Tower
88 Connaught Road Central
173 Des Voeux Road Central
Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

**Registered Office, Head Office and
Principal Place of Business in China**

No. 666 Gaoxin Road
East Lake High Tech
Development Zone
Wuhan, Hubei Province
PRC

Principal Place of Business in Hong Kong

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Joint Company Secretaries

Zheng Jianhua (鄭建華)
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Wuhan, Hubei Province
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Lai Janette Tin Yun (賴天恩)
*(associate member of The Hong Kong
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The Chartered Governance Institute in
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Authorised Representatives

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Wuhan, Hubei Province
PRC

Dr. Zhou Hongfeng (周宏峰)
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Cuishan Lantianyuan
Huanan Biguiyuan
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South Village Town
Panyu District
Guangzhou, Guangdong Province
PRC

CORPORATE INFORMATION

Audit Committee

Fu Lili (付黎黎) (*Chairwoman*)

Dr. Zhou Hongfeng (周宏峰)

Dr. Deng Yuezhen (鄧躍臻)

Nomination Committee

Dr. Zhou Pengfei (*Chairman*)

Dr. Cheng Bin (程斌)

Dr. Dai Weiguo

Remuneration Committee

Dr. Cheng Bin (程斌) (*Chairman*)

Dr. Chen Bin (陳斌)

Yuan Qian (袁謙)

Compliance Adviser

Gram Capital Limited

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Central

Hong Kong

[REDACTED]

Principal Banks

Shanghai Pudong Development Bank

Wuhan District of Hubei Free Trade Area Sub-branch

Building G-1,

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Hongshan District

Wuhan, Hubei Province

PRC

China CITIC Bank

Wuhan East Lake Sub-branch

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Hongshan District

Wuhan, Hubei Province

PRC

CORPORATE INFORMATION

China Merchants Bank
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Wuhan, Hubei Province
PRC

Company's Website

www.yzybio.com

(A copy of this document is available on the Company's website. Except for the information contained in this document, none of the other information contained on the Company's website forms part of this document)

INDUSTRY OVERVIEW

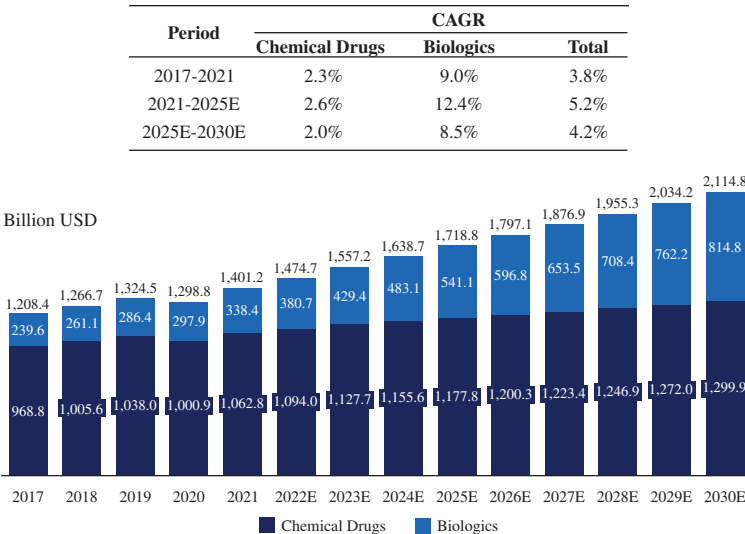
The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan 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 Sole Sponsor, 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, fairness and completeness.

GLOBAL AND CHINA PHARMACEUTICAL MARKET

Overview

The global pharmaceutical market is comprised of two segments, namely chemical drugs and biologics. As illustrated in the chart below, from 2017 to 2021, the size of the global pharmaceutical market experienced an increase from US\$1,208.4 billion to US\$1,401.2 billion, representing a CAGR of 3.8%. The size of the global pharmaceutical market is expected to continue growing in the near future and is forecasted to reach US\$1,718.8 billion and US\$2,114.8 billion in 2025 and 2030, respectively, representing a CAGR of 5.2% from 2021 to 2025 and 4.2% from 2025 to 2030.

Global Pharmaceutical Market, 2017-2030E

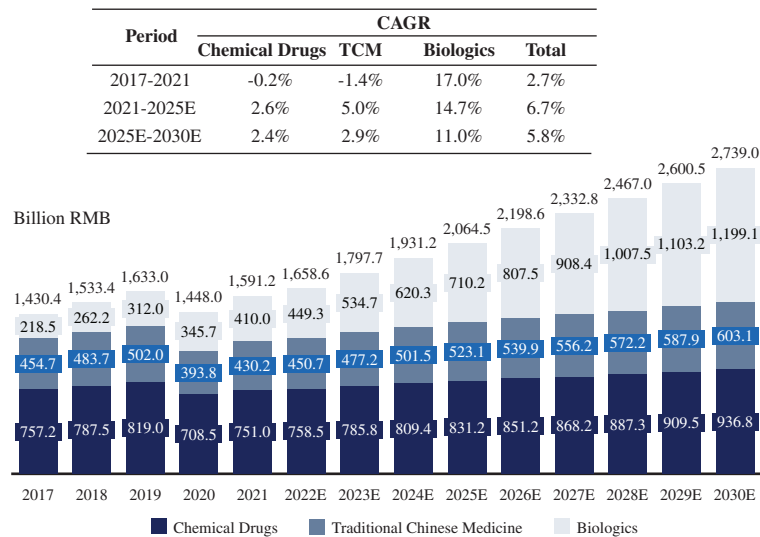


Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, Frost & Sullivan Analysis

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China’s pharmaceutical market, on the other hand, is comprised of chemical drugs, traditional Chinese medicine (TCM) and biologics. In line with the growth of the global pharmaceutical market and propelled by the economy growth and demand for healthcare in China, the size of the China pharmaceutical market increased from RMB1,430.4 billion in 2017 to RMB1,591.2 billion in 2021, representing a CAGR of 2.7%. The size of the China pharmaceutical market is projected to grow at a slightly faster pace than that of the global pharmaceutical market to reach RMB2,064.5 billion in 2025 and RMB2,739.0 billion in 2030, representing a CAGR of 6.7% from 2021 to 2025 and 5.8% from 2025 to 2030.

China Pharmaceutical Market, 2017-2030E



Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, Frost & Sullivan Analysis

GLOBAL AND CHINA ONCOLOGY DRUG MARKET

Overview

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion and which are usually classified as either hematological malignancies or solid tumors. It is the leading cause of death worldwide and is rapidly overtaking heart disease in many countries to become the number one cause of mortality. Oncology treatments have undergone significant development over the years, with chemotherapeutic drugs, targeted therapy and immune-oncology therapy becoming the major oncology treatments available to date. Chemotherapeutic drugs are the first systemic drugs to treat cancer. Although widely used in a broad range of indications, they frequently cause severe side effects. Since the early 2000s, there has been major progress in developing targeted small molecule drugs and mAbs, which have revolutionized oncology treatments, and many of them have become global blockbuster drugs. In recent years, BsAbs have attracted increasing interest in scientific and clinical research as a next-generation antibody therapy approach for the treatment of cancer. Through binding to two different antigen sites, BsAbs are able to provide robust and more specific targeting.

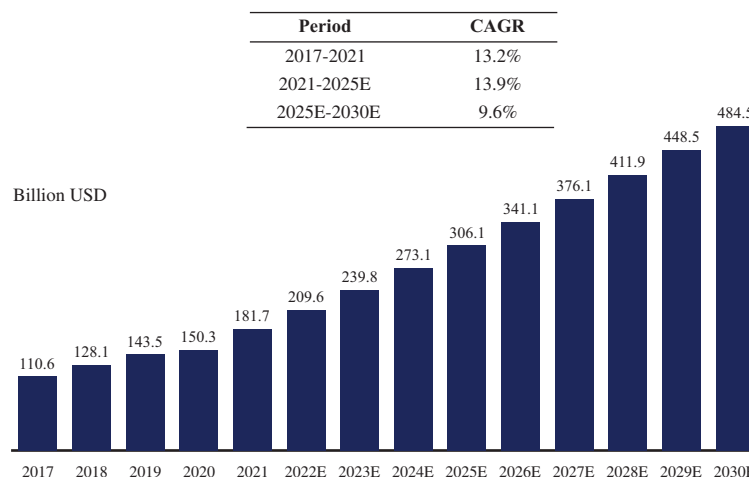
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The global and China oncology drug markets are fiercely competitive in terms of the number, modalities and expected clinical performance of currently available treatments. Major modalities of oncology therapy include chemotherapy, targeted therapies, immune checkpoint inhibitor (ICI) mAbs, cell and gene therapies (CGT), and BsAbs. Currently, there are approximately a thousand chemotherapy drugs available globally and in China for cancer treatment. For example, with respect to HER2-targeted therapies, there are currently 23 approved antibody drugs worldwide, and over 500 antibody pipelines are in the clinical phase globally. For ICI mAbs, taking anti-PD-1 mAbs as an example, there are currently 16 approved drugs globally, and over 200 pipelines are in the clinical phase. Globally, there are 6 approved cell therapy products (excluding genetically modified products) and 14 approved gene therapy products for the treatment of cancer. Many approved oncology drugs and drug candidates under clinical development have demonstrated encouraging clinical efficacy and safety profile in cancer treatment.

Compared to chemotherapy, BsAbs offer a targeted and immune-mediated approach with higher effectiveness, specificity, and fewer side effects. BsAbs and ICI mAbs both harness the immune system, but BsAbs have a higher specificity. When compared to CGT, BsAbs exhibit a similar high level of specificity and effectiveness, yet have fewer side effects and are less costly.

As illustrated in the chart below, from 2017 to 2021, the size of the global oncology drug market experienced a significant increase from US\$110.6 billion to US\$181.7 billion, representing a CAGR of 13.2%. The size of the global oncology drug market is expected to continue growing in the near future and is forecasted to reach US\$306.1 billion and US\$484.5 billion in 2025 and 2030, respectively, representing a CAGR of 13.9 % from 2021 to 2025 and 9.6% from 2025 to 2030.

Global Oncology Drug Market, 2017-2030E

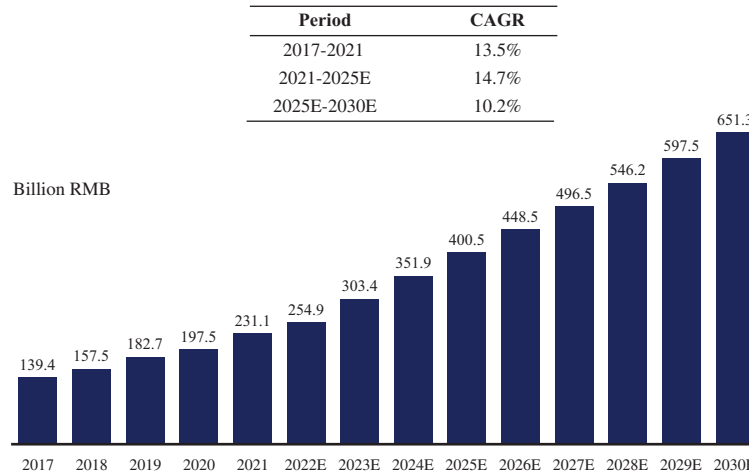


Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, IARC, GLOBOCAN, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Consistent with the growth of the global oncology drug market and driven by the steady rise of sales of oncology products in China in recent years, the size of the China oncology drug market increased from RMB139.4 billion in 2017 to RMB231.1 billion in 2021, representing a CAGR of 13.5%. The size of the China oncology drug market is projected to grow at a slightly faster pace than that of the global oncology drug market to reach RMB400.5 billion in 2025 and RMB651.3 billion in 2030, representing a CAGR of 14.7% from 2021 to 2025 and 10.2% from 2025 to 2030.

China Oncology Drug Market, 2017-2030E

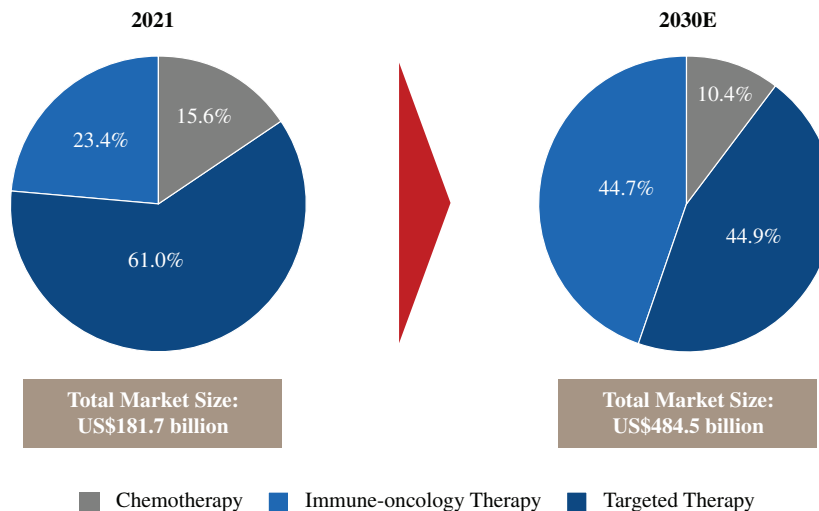


Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Global and China Oncology Market by Therapy

According to Frost & Sullivan, the global oncology market was dominated by targeted therapy, which took up to approximately 61.0% of the global market in 2021. In 2030, targeted therapy and the immune-oncology therapy are expected to account for 44.9% and 44.7% of the global oncology market, representing an aggregate market size of US\$217.5 billion and US\$216.6 billion, respectively.

Breakdown of Global Oncology Market by Therapy, 2021 and 2030E

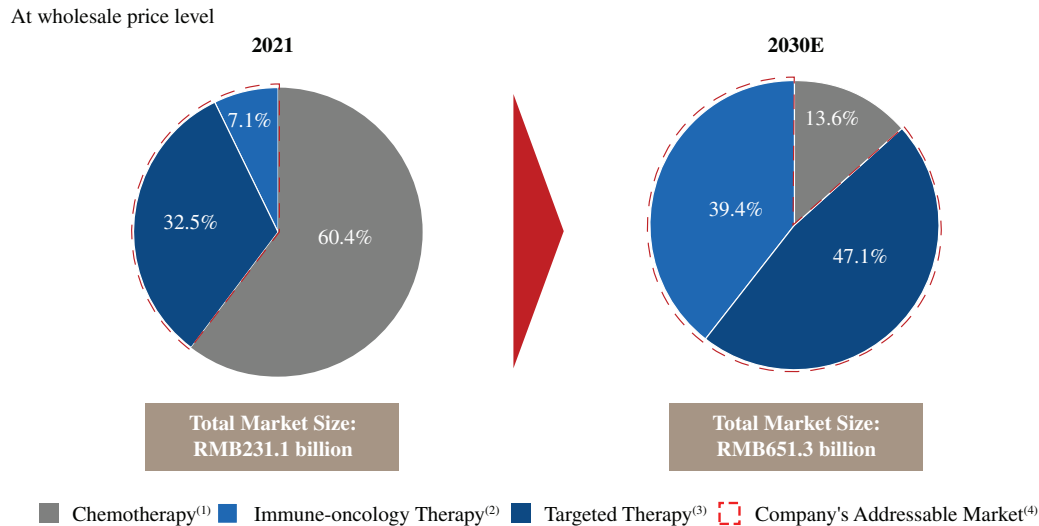


Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, IARC, GLOBOCAN, Frost & Sullivan Analysis

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In contrast, China’s oncology market in 2021 was dominated by chemotherapy drugs, which took up to approximately 60.4% of the total market. According to Frost & Sullivan, due to factors such as reimbursement policies, new drug developments and patients’ increasing affordability, targeted therapy and immune-oncology therapy are expected to occupy most of the market by 2030, with market share of 47.1% and 39.4% of China’s oncology market, respectively, representing an aggregate market size of approximately RMB306.8 billion and RMB256.6 billion, respectively.

Breakdown of China Oncology Market by Therapy, 2021 and 2030E



Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Notes:

- (1) Chemotherapy is the use of medicines or drugs to inhibit cell proliferation and tumor multiplication, thereby avoiding invasion and metastasis. These medicines may require repetition to achieve a response and do not differentiate between cancerous cells and healthy cells.
- (2) Immune-oncology therapy enhances or restores the immune system’s ability to detect and destroy cancer cells by overcoming the mechanisms by which tumors evade and suppress immune responses. Immune-oncology therapy functions through several approaches such as activating the immune system in a cytokine-dependent manner, manipulating the feedback mechanisms involved in the immune response, and enhancing the immune response via lymphocyte expansion. These techniques can be used as monotherapies or combination therapies. Common immune-oncology therapy approaches include the use of cytokines (e.g. anti-TGF-β), adoptive cell transfer, vaccines, and antibodies targeting immune checkpoints (e.g. anti PD-L1) and/or other T subsets (e.g. anti-CD3).
- (3) Targeted therapy is a type of precise cancer treatment that controls the growth, division, and metastasis of tumors through blocking essential biochemical pathways or mutant proteins that are required for tumor cell growth and survival, and has been widely utilized and proven effective in many types of solid tumors. Targeted therapy can inhibit tumor progression and induce striking regressions in molecularly defined subsets of patients. Normally, targeted therapy involves the use of antibodies or oral small drugs. Antibodies block specific targets either on the outside of cancer cells or in the tissue surrounding it (e.g. CD38, EpCAM, ANG2). Oral small drugs are smaller chemical components than monoclonal antibodies, which allows cells to absorb them better, so that they could bind to the intracellular targets (e.g. EGFR-TKI, VEGF, HER2).
- (4) As of the Latest Practicable Date, six of the Company’s seven pipeline drug candidates were BsAbs designed as either immune-oncology therapy or targeted therapy. Although immune-oncology therapy and targeted therapy are both specific methods for cancer treatment, there are some features that distinguish them from each other. Immune-oncology therapies typically enhance or restore the immune system’s ability to detect and destroy cancer cells, and targeted therapies usually eliminate tumors by blocking targets engaged in essential biochemical pathways that are required for tumor cell growth and survival. BsAbs can simultaneously target two antigens or epitopes, and this dual function enables them to simultaneously regulate immunological reactions and interfere with the essential signal pathways for tumor metastasis. These characteristics make BsAbs difficult to accurately identify as either immune-oncology therapy or targeted therapy. Consequently, while the Company’s seven BsAb drug candidates can address both immune-oncology therapy and targeted therapy markets, it is difficult to precisely categorize each of the Company’s BsAb drug candidates.

INDUSTRY OVERVIEW

Growth Drivers and Future Trends of China Oncology Drug Market

The key growth drivers of China’s oncology drug market include: (a) the increasing patient pool; (b) the medical needs due to the limited number of available oncology therapies compared to the global market; (c) the improving affordability; (d) the favorable regulatory policies issued by the Chinese government in facilitating the review for, and in encouraging the development of, innovative drugs, including the Reform of Review and Approval System for Drugs and Medical Devices to Encourage Innovation (the Opinion) (《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 CFDA in January 2018, which promotes the integration of drug registration technical standards with international standards, accelerate the drug examination and approval process, and strengthening the management for the life cycle of drugs, including BsAbs; and (e) the emergence of combination therapies which is expected to further enrich the availability of oncology therapies and drive the growth of the oncology drug market.

The future trends of China’s oncology drug market mainly include: (a) the promotion of precision treatment, as innovative targeted drugs are continuously explored, precision treatment of cancer will be applied to wider tumor-related targets; (b) wider use of combination therapies, as continuous attempts are being made to involve new drugs and new combinations such as Chimeric Antigen Receptor T-Cell Immunotherapy (CAR-T) with chemotherapy and other mAbs, which will further encourage and expedite potential effective combinations to be applied in clinical practices more extensively; (c) managing cancer as a chronic disease with the development of new treatments which extend the survival period of cancer patients; and (d) the introduction of favorable regulatory policies which will accelerate the review and approval of new drugs, and the inclusion of a variety of anti-tumor drugs in the new medical insurance catalog which greatly reduces patients’ economic burden.

GLOBAL AND CHINA ANTIBODY DRUG MARKET

Overview

Over the past decade, antibody engineering has evolved dramatically. As a result, therapeutic antibodies have become the predominant treatment modality for various diseases in recent years, and also among the best-selling drugs in the global pharmaceutical market. Antibody drugs are the largest category of therapeutic biologics, which have generally shown higher efficacy and lower toxicity in treating cancers than traditional therapies such as chemotherapy and radiotherapy. Antibodies target tumor-selective antigens with a high degree of target specificity, which reduces off-target toxicity and side effects, and have gained increasing acceptance among patients and doctors.

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According to Frost & Sullivan, antibody drugs include mAbs, BsAbs, antibody-drug conjugate (also known as conjugated monoclonal antibodies), and multi-specific antibodies. The following table sets forth the classification and comparative analysis of therapeutic antibody drugs:

Categories	Structure and Functions	Advantages	Limitations	Entry Barriers	Future Trends
Monoclonal antibody (mAb)	Monoclonal antibodies are made by identical immune cells that are from a unique parent cell. mAb can have bivalent affinity, in that they bind to the same antigenic determinant.	Proven therapeutic effect for several kinds of diseases, especially for cancers and autoimmune diseases. High homogeneity. Possibility to produce large quantities of identical antibody.	Diffuse poorly and large tumor masses may be more difficult to treat by mAb therapy. Triggering antibody-dependent cellular cytotoxicity by therapeutic antibodies faces several limitations, especially for low affinity variant of the receptor.	The difficulty of development of mAbs lies in (1) the long and complex research and development process, involving knowledge and technologies from various fields and (2) extensive laws, regulations and industry standards in drug research and development, production, operation and use, and high requirements of standardized drug development for new entrants to the pharmaceutical industry.	Focus on major diseases, support in innovation, to achieve further breakthroughs. Enhancement of the key technologies to guarantee the safety, efficacy and quality control of mAbs. Continuous improvement of domestic production equipment, increasing automation, output amplification and higher requirements for plant facilities to support the rapid expansion of mAb production scale.
Bispecific Antibody (BsAb)	A BsAb is an artificial antibody that can simultaneously bind to two different types of antigens.	Potential effects on various cancers, the application to retarget effector cells of the immune system and stimulate them through the interaction to achieve an efficient lysis of tumor cells.	Low expression of the target structures. Non-human nature, limiting the dosage that can be given to patients. More challenges in chemical, manufacturing and control development.	The difficulty of development of BsAbs lies in (1) accurate assemble of heavy and heavy chains and heavy and light chains to reduce mismatch and (2) finding suitable pre-clinical evaluation models, which could be time-consuming and prolong the development process.	Application of BsAbs in cancer treatment in combination with T cell checkpoints blocking antibodies. Development of new structures of BsAbs with strong tumor cell killing activity and low levels of cytokine release. Increased engagement of mathematical modeling and simulation in the entire BsAb development process.
Antibody-drug Conjugate (ADC)	ADC consists of antibody, linker and cytotoxin. The antibody can specifically target a specific antigen which is expressed in the tumor cells; the linker acts as a bridge for antibody and cytotoxin. The linker is cleavable or non-cleavable; the toxin small molecule should have high toxic activity and low immunity.	ADC drugs have larger tolerated doses, and smaller effective doses. ADCs are now also available in combination with other classes of drugs to enhance the effect of a single treatment. And ADC also targets non-oncology therapeutic areas.	The cytotoxin drug may be off-target in the blood, resulting in the killing of normal cells. ADC preparation cannot guarantee equal drug attachment for each antibody in each batch. Limited antigens are expressed only in tumor cells and not in normal cells.	The difficulty of development of ADC lies in (1) the design and development of a combination of antibody, linker and cytotoxin with optimized overall efficacy and safety, (2) the production of ADC and (3) application of advanced technologies, such as the biological coupling technology and the linker technology.	Modification of linkers to overcome issues in treating the multidrug resistance 1-expressing tumors. Integration of ADCs with other targeted agents and immune checkpoint inhibitors. Increased use of multiple, site-specific protein conjugation for the next generation of ADCs.
Multi-Specific Antibody (MsAb)	MsAb is an artificial antibody targeting two or more unique epitopes, which can bind more than one type of antigens.	MsAb constructs potentiate antibody-mediated effects, via simultaneously blocking multiple tumor-associated antigens, and/or triggering more intensified immune reactions. Multiple functions translate into improved response rates.	Hetero-dimerization of chains may make the molecule inefficient. Potential antigenic cytokine release syndrome. Tight white cell binding may change bio-distribution. Large molecules have less intertumoral penetration and they are hard to be cleared with risk of aggregation.	The difficulty of development of MsAbs lies in (1) their display of suboptimal physical and chemical properties, (2) challenges associated with thermal stability of MsAbs and (3) issues with proper and efficient assembly into large and complex molecular formats.	Therapeutic exploitation of intracellular neoantigens with MsAbs to overcome extracellular target scarcity. Improvement of expression and purification methods for simplifying the production of MsAbs with high yields and purity. Enhancement of computational methods for predicting antibody variants with favorable biophysical properties.

Source: Shabbir, A., Rasheed, A., Shehraz, H., Saleem, A., Zafar, B., Sajid, M., Ali, N., Dar, S. H., & Shehryar, T. (2021). Detection of glaucoma using retinal fundus images: A comprehensive review. *Mathematical biosciences and engineering: MBE*, 18(3), 2033 -2076. <https://doi.org/10.3934/mbe.2021106>; Labrijn, A. F., Janmaat, M. L., Reichert, J. M., & Parren, P. W. H. I. (2019). Bispecific antibodies: a mechanistic review of the pipeline. *Nature reviews. Drug discovery*, 18(8), 585 -608. <https://doi.org/10.1038/s41573-019-0028-1>; Gerber, D. E. (2008). Targeted therapies: a new generation of cancer treatments. *American family physician*, 77(3), 311-319.; Hollenbaugh, D., & Aruffo, A. (2002). Construction of immunoglobulin fusion proteins. *Current protocols in immunology*, 48(1), 10-19.; Bazarbachi, A. H., Al Hamed, R., Malard, F., Harousseau, J. L., & Mohty, M. (2019). Relapsed refractory multiple myeloma: a comprehensive overview. *Leukemia*, 33(10), 2343 -2357. <https://doi.org/10.1038/s41375-019-0561-2>; Ferrando-Diez, A., Felip, E., Pous, A., Bergamino Sirven, M., & Margelí, M. (2022). Targeted Therapeutic Options and Future Perspectives for HER2-Positive Breast Cancer. *Cancers*, 14(14), 3305. <https://doi.org/10.3390/cancers14143305>

INDUSTRY OVERVIEW

Fusion protein antibodies is a bio-engineered protein that joins the biologically active protein domain with the fragment of an immunoglobulin. Bifunctional fusion proteins, constructed by fusing the genes of two proteins together, combine the functions of the parent proteins in order to improve their PK and PD properties, or to introduce novel approaches in drug delivery or targeting. By fusing one or more functional fragments of parent proteins, highly efficient targeted drugs can be formed. Fusion protein antibodies have prolonged metabolism time of the active protein domain *in vivo*. However, most fusion protein antibodies have poor stability and short half-life, which requires frequent dosing and is limited in clinical application. The difficulty of development of fusion protein antibodies lies primarily in the fierce competition with existing market players. For example, various fusion protein antibodies involving non-cytokine payloads have been developed for therapeutic applications; more than a dozen of Fc fusions have received FDA approval and many more Fc fusions are at various stages of therapeutic development. Efforts will be made to minimize the off-target activity of the antibody and the active protein domain and to overcome engineering and design challenges for all classes of fusion proteins. Development of novel fusion strategies and the incorporation of peptide and protein motifs in fusion protein development will further realize the potential of fusion protein antibodies.

The advantages and distinctive characteristics of fusion protein antibodies have translated into tremendous commercial success. Regeneron, Roche, and other pharmaceutical giants have generated significant sales from fusion protein antibody drugs.

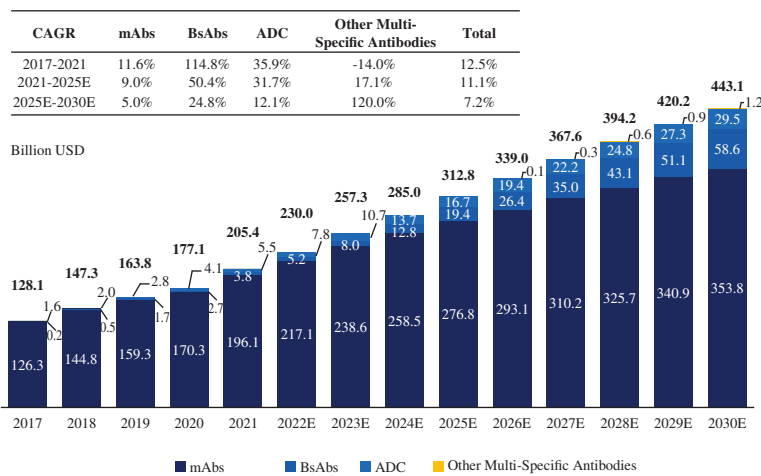
The following table sets forth a comparative analysis between BsAb and fusion protein antibodies:

Categories	Technical Challenges	Manufacturing Requirements	Molecular Stability	Clinical Efficacy
BsAb	The large molecular weight of BsAbs results in poor tumor permeability and a complex structure, which can lead to significant mismatch issues such as mismatch between heavy and light chains. Incorporating asymmetric structures can address these mismatch problems.	(1) High-throughput screening of potential therapeutic antibodies and the rapid generation of cell lines for recombinant human antibodies are necessary steps to achieve the production scale required for clinical testing. (2) The ability to genetically modify test animals to produce human antibodies is necessary. (3) Built-in purification technology is required to facilitate manufacturing at a commercial scale. (4) The production process for BsAbs is relatively mature, and the Fc region helps improve the antibody's solubility and stability, making production relatively convenient.	BsAb serum exhibits a long half-life, high molecular weight, and high stability, typically ranging from several days to tens of hours.	BsAbs are designed with two variable domains to elicit biological effects that require simultaneous binding to two targets. For instance, one variable domain can bind to tumor cells while the other variable domain can bind to cytotoxic immune cells. BsAbs are commonly utilized to treat solid tumors and solid tumors with different genetic mutations, including but not limited to lymphoma, hemophilia, leukemia, systemic lupus erythematosus, and neurodegenerative diseases such as Alzheimer's disease. The commercial clinical pipeline primarily focuses on cancer treatment and malignant tumors.
Fusion protein antibodies	Combining different components of the fusion protein that do not naturally occur together can result in instability with the composite molecule, posing manufacturing challenges such as aggregation during cell culture or purification steps. Furthermore, the fusion protein may have weak immunogenicity and require frequent administration.	The chemical manufacturing and control process for fusion proteins is more complex and less mature due to its differing structure compared to natural antibodies.	Fusion protein antibodies are primarily made up of flexible single-chain variable fragments and are considered smaller recombinant proteins that can be cleared by the kidneys. The typical serum half-life for fusion proteins is several hours which is shorter than that of BsAbs.	Fusion proteins are also frequently employed in the treatment of tumors, including solid tumors and hematological malignancies. However, the indications for fusion proteins are generally more limited, and their application range is not as broad as that of BsAbs.

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In 2021, the global therapeutic antibody market grew to US\$205.4 billion, representing a CAGR of 12.5% from 2017 to 2021, and is expected to reach US\$312.8 billion in 2025 due to rising medical demand and innovative antibody pipelines, representing a CAGR of 11.1% from 2021 to 2025, and to further increase to US\$443.1 billion in 2030, representing a CAGR of 7.2% from 2025 to 2030. The mAbs is the largest category in the global antibody market by revenue and accounted for over 95% of the market in 2021. While new biologics such as BsAbs, antibody-drug conjugates and other antibody types are still relatively new to the market, the anticipated market growth for these types of biologics is high given the breakthrough of technology and clinical studies.

Global Therapeutic Antibody Market Size, 2017-2030E



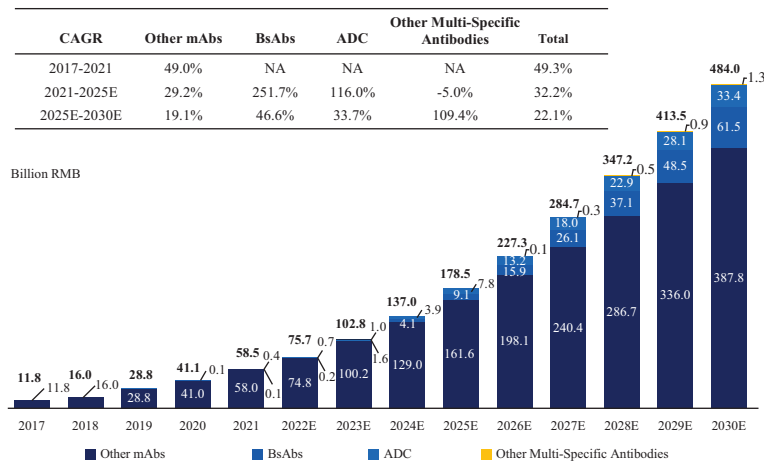
Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, IARC, GLOBOCAN, Frost & Sullivan Analysis

Note: The market size for mAbs represents the market size of mAbs other than ADC.

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China’s therapeutic antibody market, in comparison, grew to RMB58.5 billion in 2021, representing a CAGR of 49.3% from 2017 to 2021, and is expected to rapidly grow and reach RMB178.5 billion in 2025 at a CAGR of 32.2% from 2021 to 2025, and RMB484.0 billion in 2030 at a CAGR of 22.1%.

Market Size of Therapeutic Antibody Market in China, 2017-2030E



Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Growth Drivers and Future Trends of China Therapeutic Antibody Drug Market

The key growth drivers of China’s therapeutic antibody drug market include: (a) the increasing patient pool due to the rising prevalence of chronic diseases brought by an aging population, accelerated urbanization and environmental changes; (b) the favorable regulatory policies issued by the Chinese government; (c) the Chinese government’s emphasis on strengthening intellectual property protection; (d) the enlargement of the talent pool of research and development personnel that have extensive lab experience in the United States and Europe, thereby leveraging their experience to upgrade the research and development platforms of domestic companies; (e) the research and development collaboration with multinational corporations which facilitates the research and development capabilities of local players; and (f) the high market conversion rate of antibody drugs, as indications are gradually expanding to other disease areas.

The future trends of China’s therapeutic antibody drug market mainly include: (a) the growing demands of China’ antibody drugs market; (b) the progressive increase of favorable industrial policies in the antibody drugs market; (c) the high conversion rate of antibody drugs, which allows indications to expand into other disease areas; (d) the high return rate of antibody body drugs which leads to increased investment efforts from domestic pharmaceutical companies; (e) the development of new targets and therapies as a result of mAbs having a shorter history in China and the current extensive medical demands; (f) the increasing penetration of mAb drugs due to the expansion of the NRDL and the launching of biosimilars which will drive the growth of the entire pharmaceutical market; (g) the diversity of therapeutic antibody drugs as a result of rapid technological development; and (h) value creation through the continuous innovation of antibody technologies.

INDUSTRY OVERVIEW

Global and China BsAb Market

Overview

A BsAb is an artificial protein that recognizes and specifically binds two antigens or epitopes. It simultaneously blocks the biological functions mediated by both antigens/epitopes or draws the cells of both antigens closer together. In recent years, a better understanding of the pathogenesis of various diseases and the rapid development of therapeutic mAbs have also contributed to the development and advancement of BsAbs. With the development of antibody construction, expression and purification techniques, dozens of structures have emerged from BsAbs. The applications and research of existing BsAbs are mainly focused on the field of oncology therapy, but also extend to other areas such as hemophilia and ophthalmology.

The development of BsAbs is a nascent field and faces many imminent risks and challenges. BsAbs are produced through cellular expression techniques, typically incurring higher production costs than the synthesis technologies used for small molecule drugs. In addition, BsAbs cannot be administered orally, thus the less convenient administration methods of BsAbs especially intravenous administration, increases treatment costs and safety risks associated with infusions.

Compared to monospecific antibodies, the design, research, and validation of the dual-specific binding mechanism of BsAbs, along with the molecular construction and preparation of BsAbs, are significantly more complex. This increases the difficulty and risk of developing BsAbs and the difficulty and cost of their production.

Compared to cell therapies, BsAbs cannot replenish functional cells in the body. Therefore, in situations where there is a deficiency of functional cells in the body, BsAbs may not be able to achieve optimal therapeutic effects.

The construction of bispecific molecules is more complicated than that of monospecific antibodies. From 2000 to the present, pharmaceutical companies worldwide have been continuously developing different bispecific molecule platform technologies, aiming for more stable and reliable platform structures. As a result, most drug molecules began entering clinical trials after 2015. Thus, the number of approved BsAb drugs is currently limited, and there are even fewer pipelines specifically for the treatment of MA and MPE. As of the Latest Practicable Date, there were only one BsAb (catumaxomab) applying for renewal of marketing authorization and one pipeline of BsAb (M701 of the Company) under clinical development globally that were specifically developed for the treatment of MA and MPE.

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Currently, BsAbs are generally divided into two categories according to their structure: IgG-type structure and non-IgG-type structure. Between the two, the IgG-type structure can be further divided into two types: symmetric and asymmetric, where the asymmetric structure has obvious advantages. The diagram below illustrates the categories of BsAbs, including their advantages and disadvantages:



Non-IgG



Symmetric IgG



Asymmetric IgG

Advantages	• Simple structure • The clinical dosage is low, less than one-tenth of the original amount of antibodies • Weak immunogenicity	• Similar to the structure and stability of natural IgG • Mature technology, high expression	• Solved the technical limitations of Knobs-into-Holes technology in common light chain • Realizes the bivalent binding of tumor antigens, which can reduce the toxicity caused by CD3 antibodies when binding to tumor antigens
Disadvantages	• Short half-life (only 2 hours) • Unstable structure, low expression and difficult process	• Limited spatial bispecific binding effect	• Long technical route, difficult design and process

Source: *Frontiers in Immunology*, 2021: 1555., *Analysis and Characterization of Antibody-based Therapeutics*. Elsevier, 2020: 167-179., *Journal of Immunology Research*, 2019, 2019., *Antibodies*, 2018, 7(3): 28., *Journal of hematology & oncology*, 2015, 8(1): 1-14., *Frost & Sullivan Analysis*

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Comparison of BsAbs with Other Treatment Methods

Comparison with monoclonal therapies

BsAbs are structurally designed to target different antigen binding sites. For T cell-engaging BsAbs, one of their binding arms targets antigens and the other arm binds the labeled antigen on the effector T cell, which activates the effector T cells to kill tumor cells. The interaction with two different surface antigens induces the binding specificity and reduces side effects such as off-target toxicity. Further, since one disease modulator may play an essential role in several independent pathways and co-expression of different receptors has been found in many tumors, targeting two different growth-promoting receptors on a single tumor cell may increase the antiproliferative effect and help avoid the development of drug resistance. However, the safety and efficacy of BsAbs in treating cancer and its complications compared to their monoclonal antibody counterparts, which have been marketed or are currently going through clinical development in large amount, remain to be substantiated in clinical applications.

Comparison with combination therapies

The use of BsAbs compared to combination therapies with two monospecific drugs makes it possible to optimize expenses by reducing the cost of development and clinical trials. Additionally, BsAbs only require single administration compared to combination therapies that require multiple injections of two or more antibodies, simplifying the frequency and practice of administration. However, the safety and efficacy of BsAbs in treating cancer and its complications compared to combination therapies remain to be substantiated in clinical applications.

Comparison with current treatments for retinal disorders

Most treatments for retinal disorders target the vascular endothelial growth factor (VEGF), but not all patients respond to these treatments. BsAb drugs target two pathways simultaneously. Therefore, patients who are not sensitive to anti-VEGF therapies may benefit from blocking the other angiogenesis pathway. Studies have shown that more than 50% of patients were able to go 16 weeks or longer between treatments and more than 70% of patients were able to extend the treatment interval by 12 weeks or longer. However, the safety and efficacy of BsAbs in treating cancer and its complications compared to current treatments for retinal disorders remain to be substantiated in clinical applications.

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Market Size

In 2021, the global BsAb market grew to US\$3.8 billion, representing a CAGR of 114.8% from 2017 to 2021, and is expected to reach US\$19.4 billion in 2025 due to breakthroughs of technology and clinical studies, representing a CAGR of 50.4%, and to further increase to US\$58.6 billion in 2030, representing a CAGR of 24.8%. China’s BsAb market size was RMB0.1 billion in 2021, but is expected to reach RMB9.1 billion in 2025, representing a CAGR of 251.7%, and to further increase to RMB61.5 billion in 2030, representing a CAGR of 46.6%. In terms of percentage of corresponding therapeutic antibody market, the market share of BsAb drugs globally and in China in 2022 are 2.3% and 0.3%, respectively.

The rapid growth of China’s BsAb market size from 2021 to 2025 is mainly attributed to the following factors:

- (i) Starting from a small base market: As of November 2020, China had only one marketed BsAb product, Emicizumab, which was launched in November 2018. Its indication, Hemophilia A, is a rare disease with a limited patient population and modest sales, resulting in a 2021 BsAb market size of only RMB0.1 billion. Thus, the rapid growth from 2021 to 2025 begins from a very small market base.
- (ii) Rapid growth: Between December 2020 to June 2022, three BsAb products were launched in China: Blinatumomab in December 2020 and Cadonilimab in June 2022. These two products both generated substantial revenues within one to two years after their launch.
- (iii) Significant growth potential: There are multiple products expected to enter the market in the near future. Furthermore, the pace of BsAb drug development and market promotion is expected to accelerate after the impact of the COVID-19 epidemic diminishes.

China’s BsAb market is expected to grow at a CAGR of 196.0% from 2023 to 2025. According to Frost & Sullivan, the development trend of China’s BsAb market from 2023 to 2025, having four BsAb products launched in 2023 and a rich pipeline under development, is comparable to that of China’s anti-PD-1/PD-L1 mAb market from 2018 to 2020. China’s anti-PD-1/PD-L1 mAb market grew at a CAGR of 278.3% from 2018 to 2020, with four PD-1/PD-L1 products launched in 2018.

Due to the limited number of marketed BsAb products globally and domestically, and the absence of any BsAb biosimilars, the growth rate of China’s BsAb market is expected to remain high at a CAGR of 46.6% from 2025 to 2030.

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Recently, other favorable policies in China such as the NMPA’s “Opinions on Encouraging Pharmaceutical Innovation via Priority Review & Approval” (《關於鼓勵藥品創新實行優先審評審批的意見》) will also help streamline the drug approval process and accelerate drug launches in China.

Growth Drivers and Future Trends of China BsAb Market

The key growth drivers of China’s BsAb drug market include: (a) the durability of the efficacy for BsAbs, as the synergistic effects of BsAbs reduce tumor cell escape and diminish the potential side-effects caused by mAbs, which subsequently improve therapeutic efficacy. Additionally, BsAbs can potentially increase binding specificity by interacting with two different cell-surface antigens instead of one, which also brings higher safety and efficacy; and (b) a potential for multiple applications, as the dual specificity of BsAbs opens up a wide range of applications, including redirecting T cells to tumor cells, blocking two different signaling pathways simultaneously, dual targeting of different disease mediators, and delivering payloads to targeted sites.

The future trends of China’s BsAb drug market include: (a) the development of manufacturing technologies for BsAbs. The BsAb development has long been hampered by manufacturing related challenges, such as product instability, low expression yields and immunogenicity. Simplifying the structure and production procedures are keys to designing an ideal BsAb platform moving forward; (b) the continuous research and development efforts in evolving technologies that would enable BsAbs to treat solid tumors, where their treatment effects are currently limited; and (c) the expansion of indications for BsAbs, as BsAbs have the potential to go beyond the treatment of tumors and serve as an important modality for the treatment of other disease types such as inflammatory diseases; and (d) the proactive engagement of leading domestic pharmaceutical companies in the research and development of BsAbs drugs.

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OVERVIEW OF MAJOR TARGETS OF THE COMPANY’S BISPECIFIC ANTIBODY DRUG CANDIDATES

The diagram below illustrates the comparative analysis of the targets of the Company’s BsAb drug candidates:

Targets	Advantages	Limitations	Entry Barriers	Future Trends
EpCAM	EpCAM overexpresses on epithelial tumors, circulating tumor cells and cancer stem cells, and is associated with the proliferation, differentiation and adhesion of epithelial cancer cells. Because most solid tumors are of epithelial origin, EpCAM can be used as a tumor marker with potential application as effective diagnostic and therapeutic targets for multiple tumors.	The development of drugs targeting on EpCAM is difficult. EpCAM is not a very good target for mAb development, mainly because EpCAM is widely expressed on normal tissues which might cause safety issues, and mAb targeting EpCAM has limited efficacy. Lacking stratification of patients based on EpCAM makes it inefficient for clinical use.	The difficulty lies in the clinical development. There are technical barriers in the design of EpCAM targeted drugs with new mechanisms and better anti-tumor effect. More exploring studies are required in the selection of clinical indications and dosing regimens.	Developing therapies with new mechanisms, such as BsAbs, ADCs, and CAR-T cell therapies targeting EpCAM. Exploring local therapy in abdominal, thoracic, and urinary tracts. Studying EpCAM targeted drugs with companion diagnostics for cancers, establishing of precision medicine protocols, and researching the combination therapies of EpCAM targeted drugs and other drugs.
VEGF	VEGF plays important roles in angiogenesis of tumors and neovascular eye diseases, and anti-VEGF drugs have achieved great clinical benefits in oncology and ophthalmology. It is also an immunomodulator of the tumor microenvironment and promotes an immune suppressive microenvironment. VEGF targeted combination therapies with anti-PD-1 drugs have been approved for various indications such as lung cancer.	Although VEGF inhibitors showed prospective efficacy in clinical application, there are still barriers and challenges to surmount, such as to moderate clinical efficacy, mechanism-related toxicities and the occurrence of clinical resistance.	VEGF is currently one of the most popular targets and has a wide range of applications. The fierce market competition has put higher demands on the effectiveness and safety of new VEGF-based products.	Identifying novel combination strategies of VEGF inhibitors and multi-targets, especially dual-targets drug design is one of the hottest areas in tumor treatment to have synergistic antitumor effect and improved pharmacokinetic properties. Designing multi-targets drug and improving formulation for the clinical importance of VEGF for neovascular eye diseases.
HER2	HER2 overexpression is prevalent in many cancers, such as breast cancer, gastric cancer, bladder cancer, pancreatic cancer and ovarian cancer. HER2-high expression is found specifically in tumor tissue. Therefore, in the treatment of HER2-positive solid tumors, HER2 targeted therapies have better safety and efficacy than traditional chemotherapy.	The current HER2 targeted therapies have a poor effect on patients with HER2-low and -medium expression. Many patients with high HER2 over-expression still do not respond to HER2 targeted therapies, and may develop resistance to the therapies with the same mechanism after a period of treatment time.	HER2 is a well-studied therapeutic target. Currently, the competition for the developments of HER2 targeted mAbs and ADC drugs is very fierce. The entry barriers mainly include development of highly effective HER2 targeted drugs with new molecular structures, and selection of appropriate research methods for pre-clinical and clinical research.	Developing new types of HER2 targeted therapies. Exploring the combination of HER2 targeted drugs and other drug. Expanding indications of which HER2 targeted therapies can be used for treatment.
ANG2	ANG2 plays a key role in promoting angiogenesis and stability in vascular physiology. Activation of ANG/Tie2 signaling is important in the restoration of vascular integrity which is essential in the treatment of some eye disorders like DME and wAMD. In addition, ANG-2 levels are significantly elevated in the vitreous fluid of diabetic eyes, which makes it a new target of the anti-angiogenesis therapy.	The expression of ANG2 is complex, and is regulated by different mechanisms in different abnormal cells. Blocking of single ANG2 signaling is insufficient for druggability.	Because ANG1 and ANG2 are highly homologous, it is difficult to develop a targeted drug that is only specific to ANG2. For ophthalmic diseases, it is technically difficult to develop a high concentration formulations. How to improve the efficacy of ANG2 targeted drugs and to achieve industrialization are two key barriers to entry into this field.	Exploring the potential of combination therapies with other drugs to treat tumors clinically. Developing new regimens for the treatment of neovascular eye diseases.
CD38	CD38 plays vital roles in normal cell functions and tumor growth. CD38 is widely expressed on multiple hematological malignant cells with high expression level, which represents an ideal target for treatment of hematological malignant tumors, such as MM cells. Anti-CD38 mAbs kill tumor cells through ADCC, ADPC. CDC and inhibition of enzyme activity. Besides, CD38 can regulate the immunosuppressive microenvironment via its enzyme activity, adhesion effects, and crosses with other signaling pathways, which shows its potential functions in solid tumor treatment.	The ORR and the MRD clearance rates of CD38 mAbs are low, and the treated MM patients are prone to relapse.	To improve the effectiveness of this target and the clearance of MRD, breakthroughs in some new technologies and new mechanisms of action are still needed.	Developing novel drugs targeting CD38, such as BsAbs. Exploring combination regimen of CD38. Expanding CD38 in areas other than MM treatment. Strengthening the CD38 treatment for solid tumors, companion diagnostics and MRD detection.
PD-1/PD-L1	PD-1/PD-L1 targeted therapies possess broad-spectrum anti-tumor effects. Patients with effective response to PD-1/PD-L1 can achieve long-term survival with lower side effects. The treatment is readily available and inexpensive.	PD-1/PD-L1 targeted therapies are ineffective for some types of cancers. Among the effective cancers, majority of patients have no response to the PD-1/PD-L1 immunotherapy or have gained resistant.	It is difficult to improve the effectiveness of existing antibodies with a single PD-1/PD-L1 target.	Improving clinical responses based on a comprehensive understanding of the resistance mechanisms of PD-1/PD-L1 inhibitors and how to overcome them. Studying the PD-1/PD-L1 targeted BsAbs and the combination therapies of PD-1/PD-L1 blockade with adjunctive strategies.
TGF-β	TGF-β has the functions of regulating cell growth, differentiation, ECM remodeling, promoting angiogenesis, endothelial mesenchymal transition, and regulating immunity. Abnormalities of TGF-β are associated with inflammation, fibrosis, tumors, and other diseases, making it an attractive target for disease treatment.	The mechanism of the pathway is complex; TGF-β plays different roles in different stages of tumor development. Monotherapies with a single TGF-β targeted drug is still difficult to reach a desired efficacy.	Screening for drug molecules with good safety profiles and a good inhibitory effect on TGF-β pathway and obtaining ways to inhibit TGF-β to improve the therapeutic effect are two barriers to the development of this target.	Developing BsAbs with TGF-β inhibitory function and combination therapies with other drugs. Developing TGF-β-related biomarkers associated with efficacy, including cytokines, cancer stages and pathological characteristics of the tumors (degree of fibrosis, characterization of the immune microenvironment, etc.).
CD3	CD3 is the initial signal for T-cell activation and has well-defined functions. CD3 targeted mAbs result in T-cell clearance, which has practical applications in type 1 diabetes and organ transplantation. Antibodies that can target both tumor antigens and CD3 can directly activate T cells and perform immune killing function on target cells, bypassing MHC and other pathways. CD3 targeted BsAbs account for the majority of current marketed BsAbs. Compared with cell-based drug, the production of CD3 targeted therapies can be scaled up more easily, treatment costs are lower, and safety is higher.	Pre-clinical models for pharmacological efficacy evaluation with high correlation to clinical translation are difficult to establish. The activation of CD3 may increase CRS risk. The starting dose is usually low when entering the clinical trials, requiring more time for dose escalation and administration method exploration.	It is difficult to have the self-developed genetic engineering technologies of humanized activated CD3 antibodies and CD3 BsAbs. The manufacture of BsAbs, establishment and assessment of pre-clinical models and the technical complexity of clinical studies, are all barriers of this field.	Reducing the safety risk through molecular structure and affinity adjustment. Continuously expanding the application of CD3 targeted therapies in solid tumors. Conducting research on combination therapies.

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Source: Relevant research papers, such as Macdonald, J., Henri, J., Roy, K., Hays, E., Bauer, M., Veedu, R. N., Pouliot, N., & Shigdar, S. (2018). EpCAM Immunotherapy versus Specific Targeted Delivery of Drugs. Cancers, 10(1), 19. <https://doi.org/10.3390/cancers10010019>; Zhao, Y., Guo, S., Deng, J., Shen, J., Du, F., Wu, X., Chen, Y., Li, M., Chen, M., Li, X., Li, W., Gu, L., Sun, Y., Wen, Q., Li, J., & Xiao, Z. (2022). VEGF/VEGFR-Targeted Therapy and Immunotherapy in Non-small Cell Lung Cancer: Targeting the Tumor Microenvironment. International journal of biological sciences, 18(9), 3845–3858. <https://doi.org/10.7150/ijbs.70958>

Note: Local therapy refers to the topical use of drug to treat lesions.

CD3 TARGETED BISPECIFIC ANTIBODY MARKET

CD3 Targeted BsAbs

T cell-based therapies can be mainly divided into two classes depending on the different mechanisms of actions: one class against immunosuppressive factors represented by immune checkpoint inhibitors, and the other class focusing on immunostimulatory pathways represented by CAR-T cells and T cell-engaging BsAbs. CAR-T cell therapy is an adoptive cell therapy that genetically engineers T cells to express a CAR comprising intracellular T cell signaling domains and an extracellular antigen-recognition structure targeting tumor-associated antigens (TAA), redirecting and activating T cells to eradicate malignant cells. The alternative approach to redirecting T cells against target cells is T cell-engaging BsAbs which do not require genetical engineering, and bind TAAs on cancer cells and targets on T cells with their two arms, thereby engaging effective T cells and tumor cells.

CD3 is a protein complex and T cell co-receptor that is involved in activating both the cytotoxic T cell and T helper cells. These chains are associated with the T cell antigen recognition receptor (TCR) and the CD3-zeta which is a homodimer to generate an activation signal in T lymphocytes. Due to the invariant property of CD3 chains in the TCR, CD3 is always selected as cell surface target. The CD3 BsAbs can employ different types of T cells and are not limited to tumor-specific T cells, contrary to the key requirement for effective immune checkpoint therapy. CD3-targeting and T cell-engaging BsAbs require complete suppression of fragment crystallizable-mediated effector functions in order to minimize off-target toxicity and to maximize therapeutic efficacy. In recent years, CD3 has been an emerging target in BsAbs development for cancer treatment. Around 45% of globally marketed BsAbs and BsAbs in clinical development target CD3.

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As of the Latest Practicable Date, with respect to the indications covered by the Company’s existing pipeline for cancer treatment, there was one CD3 targeted antibody drug approved for the treatment of multiple myeloma (MM) and one for the treatment of uveal melanoma globally. No other marketed CD3 targeted antibody drug has been approved for the treatment of MM, solid tumors, MA and MPE. The following table sets forth the details of the two aforementioned marketed CD3 targeted antibody drugs globally as of the Latest Practicable Date:

Global Marketed Drugs							
Product	Drug Name	Developer	Target	Drug Type	Indication	Approval Date	Price (USD)
TECVAYLI	Teclistamab	Janssen Biotech, Inc.	BCMA, CD3	BsAb	MM	October 25, 2022	10mg/ml 3ml: 1,873
KIMMTRAK	Tebentafusp	Immunocore Ltd.	GP100, CD3	ADC	Uveal Melanoma	January 25, 2022	100mcg/0.5ml 0.5ml: 20,257

Source: FDA, NKEXnews, Annual Reports of Listed Medical Companies, Clinical Trials, Frost & Sullivan

As of the Latest Practicable Date, there were 75 and 21 CD3 targeted antibody drug candidates or fusion proteins for the treatment of MA, MPE, MM and solid tumors under clinical development globally (excluding China) and in China, respectively, according to the CDE and the ClinicalTrials.gov websites.

Scientific Barriers to CD3 Targeted BsAbs

The development of CD3 targeted BsAb drugs currently faces challenges including: (a) the risk of on-target off-tumor toxicities on solid tumors, since solid tumor-associated antigens are often also expressed on tissues of healthy organs, which can lead to immune pathology and organ failure with potential fatality; (b) the complex structural characteristics of the CD3 protein which leads to difficulties in designing effective compounds with specific binding according to their structure; and (c) the presence of multiple immunosuppressive cell types in the tumor microenvironment of solid tumors, which compromises the quality of effector T cells, and reduces the effectiveness of the immunological synapse created by the CD3 targeted BsAbs.

Future Trends of CD3 Targeted BsAbs

The future trends of CD3 targeted BsAbs mainly include: (a) the potential combination of CD3 BsAbs with other therapies to reach better treatment outcomes; (b) the increased focus on solid tumors, as several CD3 BsAbs have been successfully used in the clinic for the treatment of hematologic tumors, the indications are actively expanding towards solid tumors; and (c) the proactive development of new strategies to mitigate the toxic side effects of CD3 BsAb treatments.

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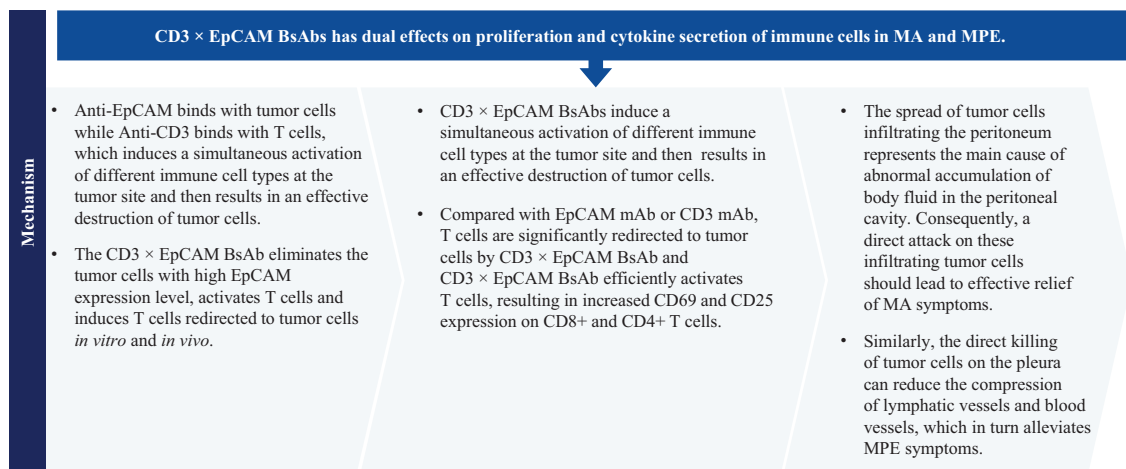
EpCAM × CD3 Targeted BsAb

Mechanisms of EpCAM × CD3 Targeted BsAbs

EpCAM is an attractive target for antibody therapy of oncology. EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens and can be observed in over 90% of common types of cancers causing malignant ascites and malignant pleural effusion.

The development of anti-EpCAM and anti-CD3 BsAbs provide an emerging alternative to address the scientific barriers to CD3 targeted BsAbs.

The diagram below illustrates the mechanism of action of EpCAM × CD3 targeted BsAb in malignant ascites (MA) and malignant pleural effusion (MPE) treatments:



Source: *Medicina*, 2019, 55(8): 490., *Cellular and Molecular Life Sciences*, 2018, 75(3): 509-525., *Cancer treatment reviews*, 2010, 36(6): 458-467., *International journal of cancer*, 2014, 135(11): 2623-2632., *Blood, The Journal of the American Society of Hematology*, 2001, 98(8): 2526-2534., *Frost & Sullivan Analysis*

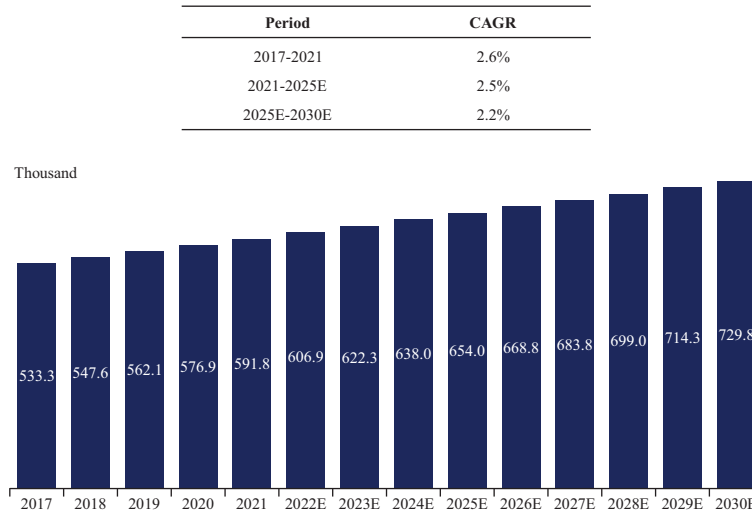
Malignant Ascites (MA) and Malignant Pleural Effusion (MPE)

MA is the accumulation of fluid in the peritoneal cavity resulting from the growth of primary or metastatic malignant neoplasms in the peritoneum. MA may be associated with a variety of neoplasms, including ovarian, breast, gastric, lung, and pancreatic cancers. MPE is the collection of fluid in the pleural cavity resulting from malignant disease. Malignant pleural effusions often contain free floating malignant cells. This can cause the patient to feel short of breath and/or experience chest discomfort. MPE is a fairly common complication in different cancers. The most common etiologies for MPE are lung cancer, breast cancer, lymphoma, ovarian cancer and gastric cancer. MPE is observed on approximately 45% lung cancer patients, 2% to 11% breast cancer patients, 41.6% lymphoblastic lymphoma patients, and 33% ovarian cancer patients.

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The incidence of MA in China has grown from 533.3 thousand in 2017 to 591.8 thousand in 2021, representing a CAGR of 2.6%. It is expected that the prevalence will increase to 654.0 thousand in 2025, and 729.8 thousand in 2030, at a CAGR of 2.5% and 2.2%, from 2021 to 2025 and from 2025 to 2030, respectively.

China Incidence of MA, 2017-2030E



Source: NCCR, *Practical Pharmacy and Clinical Remedies*. 2020,23(10):905-908., *Chinese Journal of Gastroenterology and Hepatology*. 2017, *Hepatology International*. 2013 Mar;7(1):188-198., 26(04):476-478., Frost & Sullivan Analysis

According to Frost & Sullivan, the addressable MA patients of M701 in China in 2030 is estimated to be 540.7 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable MA Patients of M701 in China	Unit	2030E
Incidence of MA ⁽¹⁾	Thousand	729.8
Treatment Rate ⁽²⁾	%	82.3
Local Therapy Rate ⁽³⁾	%	90.0
Addressable Patients⁽⁴⁾	Thousand	540.7

Notes:

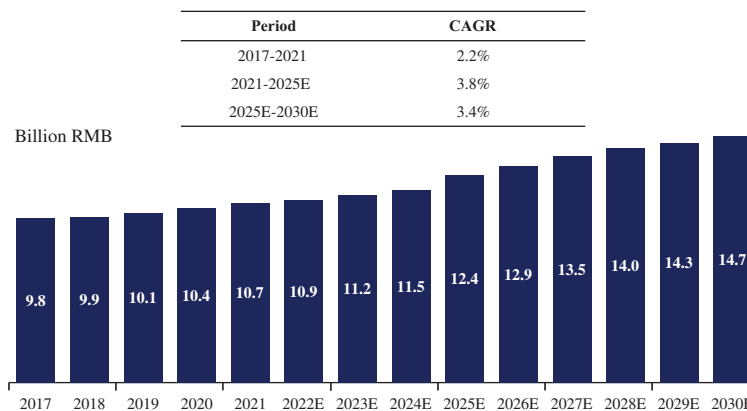
- (1) The source of MA incidences in China is Globocan.
- (2) Treatment Rate means the percentage of MA patients who are willing to receive any treatment for MA.
- (3) Local Therapy Rate means, out of all the MA patients who are willing to receive any treatment for MA, the percentage of such patients who need to receive local therapy for MA (as versus to systematic treatment for tumor control).

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- (4) MA patients who are willing to receive any treatment for MA and is in need of a local therapy are addressable patients for M701 (i.e., by assuming that all the MA patients that are willing to receive any treatment for MA and is in need of a local therapy may choose to use M701). In this table, the number of addressable patients (540.7 thousand) is arrived by multiply the Incidence of MA by the Treatment Rate and Local Therapy Rate (729.8 thousand * 82.3% * 90.0%).

The market size of MA therapies grew from RMB9.8 billion in 2017 to RMB10.7 billion in 2021, representing a CAGR of 2.2%. It is predicted that the number will continue to grow, and reach RMB12.4 billion by the year of 2025, and RMB14.7 billion by the year of 2030, with CAGR of 3.8% and 3.4%, respectively. Taking into consideration the relatively small patient group size for MA, the market size for MA treatment is relatively significant because approximately 50%-60% of MA patients opt for the expensive anti-angiogenesis drugs to manage MA, despite that many current medical treatment methods for MA, primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature.

China Market Size of MA Therapies, 2017-2030E



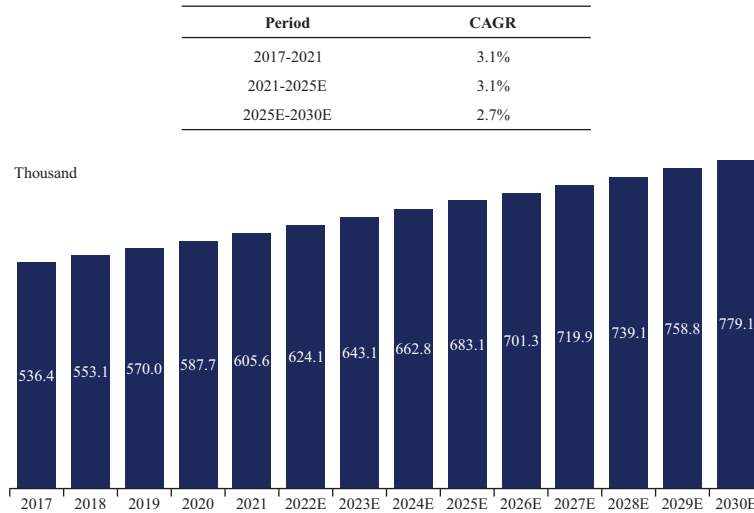
Source: Annual Reports of Listed Medical Companies, NCCR, MOHRSS, Practical Pharmacy and Clinical Remedies. 2020,23(10):905-908., Chinese Journal of Gastroenterology and Hepatology. 2017, Hepatology International. 2013 Mar;7(1):188-198., 26(04):476-478., Frost & Sullivan Analysis

Comparing with the rapid growth of the oncology drug market in China (which is projected to reach RMB400.5 billion in 2025 and RMB651.3 billion in 2030, representing a CAGR of 14.7% from 2021 to 2025 and 10.2% from 2025 to 2030), the overall growth rate for the China market size of MA therapies is comparatively stable, mainly as (a) the continually emerging expensive innovative treatment pipelines in the China oncology drug market, whereas (b) the relatively slower pace in the launch of expensive, innovative MA therapies in China market.

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The incidence of MPE in China has grown from 536.4 thousand in 2017 to 605.6 thousand in 2021, representing a CAGR of 3.1%. It is expected that the prevalence will increase to 683.1 thousand in 2025, and 779.1 thousand in 2030, at a CAGR of 3.1% and 2.7%, from 2021 to 2025 and from 2025 to 2030, respectively.

China Incidence of MPE, 2017-2030E



Source: NCCR, Medicine, 2020, 99(39)., Journal of ethnopharmacology, 2020, 249: 112412, Journal of Practical Oncology 2021, 36(01): 89-94, Frost & Sullivan Analysis

According to Frost & Sullivan, the addressable MPE patients of M701 in China in 2030 is estimated to be 552.1 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable MPE Patients of M701 in China	Unit	2030E
Incidence of MPE ⁽¹⁾	Thousand	779.1
Treatment Rate ⁽²⁾	%	78.7
Local Therapy Rate ⁽³⁾	%	90.0
Addressable Patients⁽⁴⁾	Thousand	552.1

Notes:

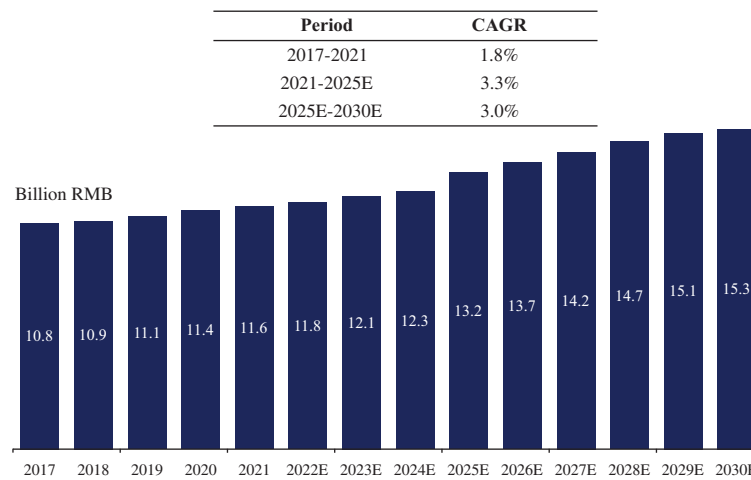
- (1) The source of MPE incidences in China is Globocan.
- (2) Treatment Rate means the percentage of MPE patients who are willing to receive any treatment for MPE.
- (3) Local Therapy Rate means, out of all the MPE patients who are willing to receive any treatment for MPE, the percentage of such patients who need to receive local therapy for MPE (as versus to systematic treatment for tumor control).

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- (4) MPE patients who are willing to receive any treatment for MPE and is in need of a local therapy are addressable patients for M701 (i.e., by assuming that all the MPE patients that are willing to receive any treatment for MPE and is in need of a local therapy may choose to use M701). In this table, the number of addressable patients (552.1 thousand) is arrived by multiply the Incidence of MPE by the Treatment Rate and Local Therapy Rate (779.1 thousand * 78.7% * 90.0%).

The market size of MPE therapies grew from RMB10.8 billion in 2017 to RMB11.6 billion in 2021, representing a CAGR of 1.8%. It is predicted that the number will continue to grow, and reach RMB13.2 billion by the year of 2025, and RMB15.3 billion by the year of 2030, with CAGR of 3.3% and 3.0% respectively. Taking into consideration the relatively small patient group size for MPE, the market size for MPE treatment is relatively significant because approximately 50%-60% of MPE patients opt for the expensive anti-angiogenesis drugs to manage MPE, despite that many current medical treatment methods for MPE, primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature.

China Market Size of MPE Therapies, 2017-2030E



Source: Annual Reports of Listed Medical Companies, NCCR, MOHRSS, Medicine, 2020, 99(39)., Journal of ethnopharmacology, 2020, 249: 112412, Journal of Practical Oncology 2021, 36(01): 89-94, Frost & Sullivan Analysis

Comparing with the rapid growth of the oncology drug market in China (which is projected to reach RMB400.5 billion in 2025 and RMB651.3 billion in 2030, representing a CAGR of 14.7% from 2021 to 2025 and 10.2% from 2025 to 2030), the overall growth rate for the China market size of MPE therapies is comparatively stable, mainly as (a) the continually emerging expensive innovative treatment pipelines in the China oncology drug market, whereas (b) the relatively slower pace in the launch of expensive, innovative MPE therapies in China market.

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Competitive Landscape of MA and MPE Treatments

The currently available MA and MPE treatments mainly focus on curing primary tumors in early-stage patients or relieving symptoms in advanced cancer patients. However, MA and MPE are frequently associated with malignancies in several organs that have poor prognosis; therefore, advanced cancer patients rarely benefit from marketed drugs. To address this issue, innovative drugs specific to MA and MPE are currently under development.

The favorable results of the Phase I/II study on catumaxomab for MPE treatment demonstrated the efficacy of EpCAM × CD3 targeted BsAbs in MPE treatment. The Phase I clinical trial of catumaxomab in treating solid tumors has indicated that the intravesical therapy with catumaxomab is well tolerated and shows encouraging preliminary efficacy in patients with high-risk non-muscle-invasive bladder cancer.

According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins, as illustrated below.

Global Pipeline							
Product	Developer	Highest Clinical Stage	Indication	Region	Drug Type	Target	First Posted Date ⁽¹⁾
Catumaxomab	TRION Pharma GmbH and Neovii Biotech GmbH	Approved in 2009, withdrew from market in 2017, applied for renewal of the marketing authorization in 2022	Cancer, Neoplasms, Carcinoma, MA	France, Germany, Italy, Spain	BsAb	EpCAM, CD3	—
ENDOSTAR™	Jiangsu Sincere Pharmaceutical Co., Ltd.	Phase III	MPE, Malignant Peritoneal Effusion	China	Other Protein	Endostatin	2021/05/27
M701	the Company	Phase II	MA	China	BsAb	EpCAM, CD3	2021/07/23
M701	the Company	Phase Ib/II	MPE	China	BsAb	EpCAM, CD3	2022/08/08
GAIA-102	Gaia BioMedicine Inc; Kyushu University Hospital	Phase II	MA, Stomach Neoplasms, Pancreatic Neoplasms, Carcinoma, NSCLC	Japan	Cell Therapy	—	2021/11/19
RSO-021	RS Oncology LLC	Phase I/II	MPE, Malignant Pleural Mesothelioma, Mesothelioma, Solid Tumor	United Kingdom	Polypeptide	—	2022/02/07
VAK	Wuhan Binhui Biotechnology Co., Ltd.	Phase I	MPE, Malignant Peritoneal Effusion	China	Cell Therapy	—	2022/09/29
IFN-γ and CIK cells, Tcm cells or CAR-T cells	Affiliated Hospital of Jiangnan University	Phase I	MPE	China	Cell Therapy	—	2022/03/07

Source: NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

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Among them, catumaxomab (developed by TRION Pharma GmbH and Neovii Biotech GmbH) is the world’s first marketed BsAb and has two targets identical to M701 which was approved in 2009 for the treatment of MA. Upon the initial commercial launch of catumaxomab in 2009, based on public information, the medical community’s understanding of immunotherapy and BsAb was not fully developed, which limited the comprehension of the mechanism of actions of catumaxomab, resulting in a relatively cautious approach towards the clinical application of the drug. Moreover, based on public information, the developers of catumaxomab fell short in formulating a market-oriented marketing strategy for catumaxomab, which led to poor sales performance after its launch and its subsequent withdrawal from the market in 2017. Catumaxomab was marketed in Europe only and the withdrawal of catumaxomab only impacted the Europe market. The withdrawal of catumaxomab was primarily due to timing and sales strategy instead of safety and efficacy concerns. Despite of that, as the world’s first BsAb drug, the withdrawal of catumaxomab did impact the overall perception of BsAbs within the medical community for a period of time. However, this perception has gradually improved with the increase in marketed BsAb drugs and their clinical use. Catumaxomab demonstrated manageable safety and encouraging efficacy during its clinical use. Therefore, the developers of catumaxomab applied for the renewal of the EMA marketing authorization of the drug for the treatment of MA in August 2022, which is currently under review.

In addition, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in a Phase III clinical trial for stomach neoplasms, advanced gastric carcinoma with peritoneal metastasis, and a Phase I/II clinical trial for non-muscle-invasive bladder cancer in China. Based on publicly available information, LintonPharm are developing catumaxomab in collaboration with LINDIS Biotech, a research partner of TRION Pharma GmbH. LINDIS Biotech is also evaluating catumaxomab in a Phase I clinical trial for urinary bladder neoplasms in German. Catumaxomab was marketed in Europe only and the withdrawal of catumaxomab only impacted the Europe market.

As advised by Frost & Sullivan and according to public information, the following table sets forth BsAb pipelines targeting EpCAM and CD3 and mAb, antibody fusion protein and CAR-T pipelines targeting EpCAM currently under clinical development globally. As of the Latest Practicable Date, these competitors have not developed their EpCAM × CD3 drug candidates for the treatment of MA/MPE, however there is no guarantee that they will not expand into the MA/MPE treatment market with these drug candidates in the future.

Product	Developer	Drug Type	Target	Highest Clinical Phase	Region	First Posted Date	Indication
BA3182	BioAtla	BsAb	EpCAM, CD3	I	United States	4/1/2023	Advanced Adenocarcinoma
M701	Our Company	BsAb	EpCAM, CD3	I/II	China Mainland	9/30/2022	MA, MPE, Solid Tumor
Catumaxomab	LintonPharm Co., Ltd.	BsAb	EpCAM, CD3	III	China Mainland	10/6/2020	Stomach Neoplasms Advanced Gastric Carcinoma With Peritoneal Metastasis, Non-Muscle-Invasive Bladder Cancer
Catumaxomab	LINDIS Biotech	BsAb	EpCAM, CD3	I	German	7/7/2020	Urinary Bladder Neoplasms
AM-928	AcadeMab Biomedical	mAb	EpCAM	I	United States	1/7/2023	Solid Tumors
VB4-845	Qilu Pharmaceutical Co., Ltd.	Antibody fusion protein	EpCAM	III	China Mainland	4/13/2021	Non-Muscle Invasive Bladder Cancer
TM4SF1- positive chimeric antigen receptor T-cell therapy, EpCAM- positive chimeric antigen receptor T-cell therapy	Shanghai Biomedunion Biotechnology Co., Ltd.	CAR-T	EpCAM, TM4SF1	NA	China Mainland	10/29/2019	Solid Tumors

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

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In addition to the above pipelines, Amgen Inc. commenced a multicenter Phase I clinical trial of solitomab, a bispecific EpCAM×CD3 T-cell engager BsAb in patients with refractory solid tumors in 2008. According to public information, Amgen Inc. has removed solitomab from its pipeline update since 2015, indicating that it may have suspended the clinical development plan for the drug candidate. We have not learned from public information that solitomab has safety or effectiveness issues. Amgen’s suspension of this pipeline may be due to strategic considerations.

In terms of MA and MPE treatment, other proteins refer to protein drugs other than mAbs, BsAbs, MsAbs, or antibody fusion proteins, which include cytokines, growth factors, or truncated forms of factors such as IL-2 and endostatin. In short, other proteins do not contain any fragments of antibodies as they are commonly broad-spectrum inhibitors without particular targets. As a result, when compared with BsAbs that have specific targets, other proteins display lower selectivity and lower efficacy.

Treatment Paradigm for MA and MPE in China

The following table sets forth the treatment paradigm for MA and MPE in China and globally. Given that MA and MPE are complications of cancer and the limited numbers of drug candidates approved for MA and MPE, the current treatment paradigm for MA and MPE do not distinguish between first-line/second-line/late-line therapies.

Treatment Paradigm of MPE ⁽¹⁾		
Thoracentesis	Pleurodesis	Indwelling Pleural Catheter (IPC)
Thoracentesis is an aprocedure where oncologists or thoracic surgeon may use to draw the fluid or air out from the pleural cavity, which could relieve the dyspnoea or other complications.	Pleurodesis is a procedure in which a chemical is administered into the chest cavity after the pleural fluid has been drained to promote adhesion between the lung and chest wall, there by reducing the risk of new fluid build-up. This procedure can be performed either by placing a small catheter between the ribs into the fluid and administering the chemical through the tube or by using thoracoscopy to spray the chemical onto the inside of the chest wall within the pleural space.	An indwelling pleural catheter is a small catheter that is inserted under the skin and into the pleural fluid, which enables repeated drainage at home to alleviate symptoms. These catheters are implanted as an outpatient procedure using local anesthesia. The catheter may help the lung eventually fully expand up to the chest wall. In many patients, once the fluid build-up is resolved, the catheter can be removed after 2-3 months.
Treatment Paradigm of MA		
Conventional Management	Hyperthermic Intraperitoneal Chemotherapy	Newer modalities
- Therapeutic paracentesis is a useful option for achieving rapid symptom relief. Large volume paracentesis, up to 5 liters, can be performed without significant complications. - Peritoneovenous shunts are recommended when the patient’s life expectancy is more than 3 months.	The rationale behind hyperthermic intraperitoneal chemotherapy includes cytoreduction by prolonged contact with tumor nodules, selective cytotoxicity due to protein denaturation, impaired DNA repair due to hyperthermia, and hyperthermia-induced vasodilation, which improves tumor oxygenation.	Treatment of antibodies against cellular adhesion molecules (e.g., EpCAM) such as Catumaxomab after therapeutic paracentesis have been linked to prolonged paracentesis-free survival, enhanced quality of life, and extended overall survival.

 Intended position and clinical focus of the Company’s drug candidate

Source: CMA, Biospace, The Oncology Nurse

Note:

(1) According to Frost & Sullivan, M701 represents an innovative treatment for MPE and has not yet been included in the treatment paradigm of relevant clinical guidelines.

The following table sets forth the features and limitations of different treatment therapies.

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The following table sets forth features and limitations of treatments for MA and MPE patients.

Treatment	Features	Limitations
Surgical Procedures ⁽¹⁾	Therapeutic paracentesis and indwelling drainage catheter could directly remove the effusions and relieve the symptoms, such as chest/abdominal pain, difficulty breathing and intestinal obstruction. Most widely accepted palliative treatments in several guidelines for MA/MPE management.	Surgical treatments cannot stop relapse of effusions accumulation and symptoms, which requires repeated surgical paracentesis, and lead to several complications, including hypoalbuminemia, pneumothorax, bleeding and intestinal obstruction. Those complications will lead to increased morbidity, mortality, and healthcare cost.
	Chemotherapy	Chemotherapy is not an approved or recommended option for MPE/MA treatment due to limited efficacy, high relapse rate and insufficient clinical evidence. Repeated local chemotherapy may cause the peritoneal adhesion which will prevent further treatments. Also, the chemotherapy always causes side effects such as hematopoietic cytotoxicity, fatigue, nausea and hair loss etc.
Local Therapy	Pleural sclerosis	Pleurodesis cannot be applied for MA in China due to lack of medical talc powder and it is only suitable for MPE treatment. Due to its relatively large side effects, it is only suitable for patients with good physical conditions.
	Immunosuppressants	Immunosuppressants are not an approved and recommended option for MPE/MA treatments due to limited efficacy, high relapse rate and insufficient clinical evidence.
	Anti angiogenic drugs	Anti-angiogenic drugs are not approved and recommended for MPE/MA treatment due to limited efficacy, high relapse rate, and insufficient clinical evidence. The anti-angiogenic drugs usually required combination treatments to achieve better effects.
	New modalities	Currently, there are no clinical trials that can prove its efficacy.

Intended position and clinical focus of the Company’s drug candidate

Source: CSCO, NCCN

Abbreviation: Local therapy refers to the topical use of drug to treat lesions.

Note:

(1) Surgical procedures includes thoracentesis, pleurodesis, and indwelling pleural catheter for the treatment of MPE and therapeutic paracentesis (one of conventional management procedure) for the treatment of MA.

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Currently, chemotherapy, immunosuppressants, and anti-angiogenic drugs have not been approved by the NMPA for the treatment of MA or MPE or included in the recommendations of clinical guidelines for MA or MPE in China. These therapies are listed in the table of features and limitations of treatments for MA and MPE above because they are incorporated into certain expert consensus for the treatment of MA and MPE in China. Expert consensus is usually based on weak evidence from one or two non-registration clinical studies, which makes it less influential in guiding clinical practice. In contrast, clinical guidelines are generally based on the results of large-scale randomized controlled Phase III trials and are widely recognized by clinicians.

Future Trends and Needs of MA and MPE Treatment

The future trends of the treatment of MA and MPE treatment mainly include: (a) the development of biomarkers as diagnostic and monitoring tools for MA and MPE, which is part of the current movement towards personalized medicine; (b) the continuous research and innovation of prominent pharmaceutical companies which will contribute to a more effective and cost-effective treatment; and (c) treatments gravitating towards patient outcomes and quality of life.

Despite of the continuous development of therapies to treat MA and MPE, there remain medical demands for innovative treatment options, mainly due to the following: (a) the distinct disadvantages of current treatments for MA and MPE, including causing significant patient discomfort and risks, and diminishing efficacy with tumor progression; (b) the lack of standard treatment guideline for MA globally and in China. Different guidelines have different mechanisms on the management of MA, and relevant studies have shown significant heterogeneity in the quality, recommendations and level of evidence among different treatment guidelines, and even within the same guidelines. Therefore, the current treatment options could not meet the demands of the patients, and a standard treatment with proven efficacy and favorable safety profile is desired by the market; and (c) MPE, as an aggressive disease, is not curable for most MPE patients; therefore, the aim of treatment for MPE is mainly palliative. Further, MPE has a uniformly fatal prognosis and a life expectancy of only three to twelve months, and currently most of the drugs for MA and MPE can only relieve symptoms but are rarely effective in increasing survival rate. The development of an effective targeted therapy is therefore desired by the patients.

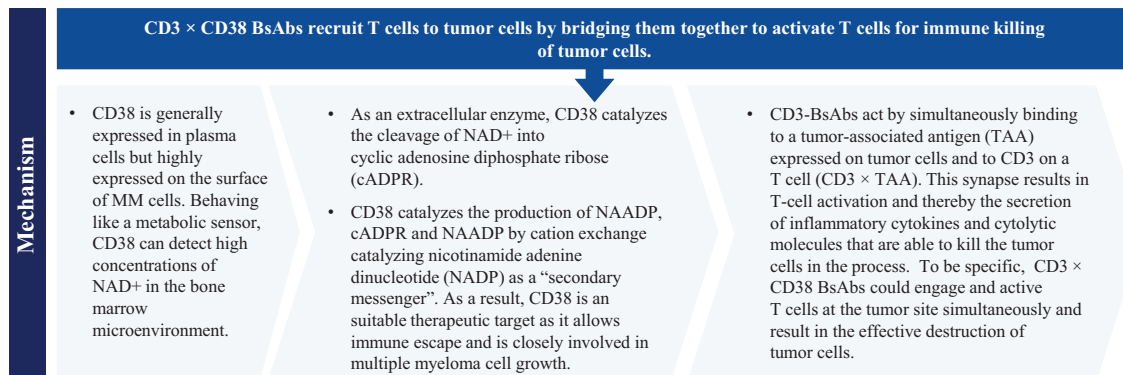
CD38 × CD3 Targeted BsAbs

Mechanisms of CD38 × CD3 Targeted BsAbs

The CD38 antigen is highly and uniformly expressed on plasma cells and therefore represents an ideal target for the treatment of multiple myeloma with anti-CD38 mAbs. A CD38 × CD3 BsAb is designed to bind both CD38 on target MM tumor cells and CD3 on T cells, allowing activated T cells to attack target tumor cells. When compared with mAb products with the same target, the CD38 × CD3 BsAb has the advantages of better efficacy, less likely to

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develop drug resistance and smaller dosage. The expected effective dose of the CD38 × CD3 BsAb is 1/20 of that of mAbs, which can significantly reduce drug costs and improve the quality of patients’ survival. The following diagram illustrates the mechanism of action of the CD38 × CD3 BsAbs.



Source: *Medicina*, 2019, 55(8): 490., *Cellular and Molecular Life Sciences*, 2018, 75(3): 509-525., *Cancer treatment reviews*, 2010, 36(6): 458-467., *International journal of cancer*, 2014, 135(11): 2623-2632., *Blood, The Journal of the American Society of Hematology*, 2001, 98(8): 2526-2534., *Frost & Sullivan Analysis*

Multiple Myeloma (MM)

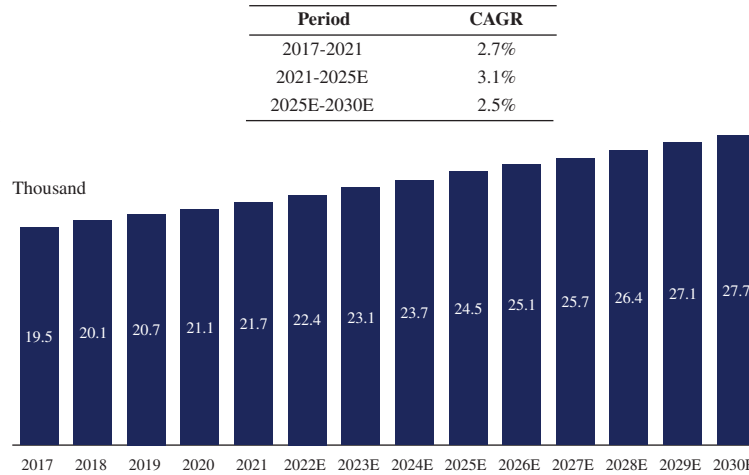
MM is a cancer of the plasma cells in the bone marrow. Plasma cells are antibody-producing white blood cells that are critical to the immune system. Myeloma begins when healthy plasma cells become cancerous and grow out of control. MM often results in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.

The prognosis of a MM patient is very heterogeneous and is subject to various factors, such as genetics, performance status and stage of disease, which in turn determine the treatment and management of the disease. Current treatment regimens can prolong patient survival only and patients will eventually relapse and succumb to their disease. For most of the patients, MM will eventually develop into rrMM. This makes patients require continuous treatment in order to manage MM as a chronic disease and prefer treatment regimens with convenient administration. Existing treatment options with different mechanisms of action are usually exhausted early on in the treatment, as patients are treated with doublet and triplet combination regimens in early treatment lines. Therefore, new classes of therapy with innovative mechanisms of action are required for patients that relapse or are refractory to the current classes of drugs.

As illustrated in the diagram below, the annual incidence of MM in China has grown from 19.5 thousand in 2017 to 21.7 thousand in 2021, representing a CAGR of 2.7%. It is expected that the prevalence will increase to 24.5 thousand in 2025 and 27.7 thousand in 2030 at a CAGR of 3.1% and 2.5% from 2021 to 2025 and from 2025 to 2030, respectively.

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China’s Incidence of MM, 2017-2030E



Source: NCCR, Frost & Sullivan

According to Frost & Sullivan, the addressable rrMM patients of Y150 in China in 2030 is estimated to be 60.4 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable rrMM Patients of Y150 in China	Unit	2030E
Incidence of MM ⁽¹⁾	Thousand	27.7
rrMM Prevalence ⁽²⁾	Thousand	84.4
Treatment Rate ⁽³⁾	%	85.8
2nd-Line Treatment Rate ⁽⁴⁾	%	83.5
Addressable Patients⁽⁵⁾	Thousand	60.4

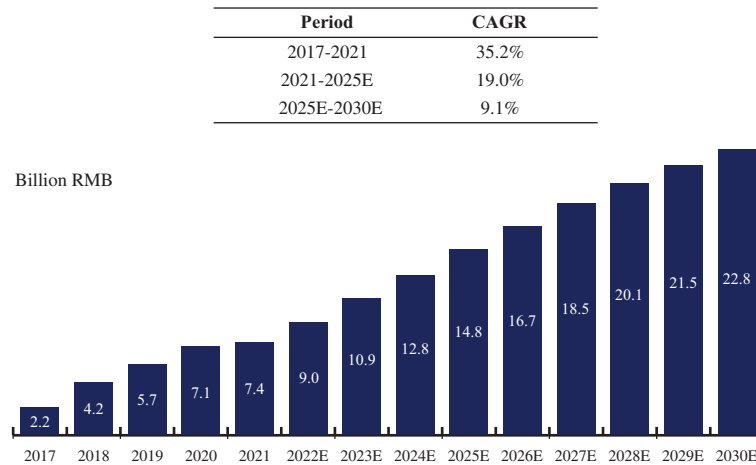
Notes:

- (1) The source of MM incidences in China are National Cancer Registry and International Agency for Research on Cancer.
- (2) The prevalence of rrMM is calculated by accumulating the number of MM patients who progress to rrMM over the years and subtracting the number of deceased patients from that population. According to the Second China Hematology Development Conference, almost all MM patients will eventually relapse, and the 5-year recurrence rate of MM is nearly 70%.
- (3) The 1st-line treatment rate and 2nd-line treatment rate of rrMM are around 85.8% and 83.5%, respectively.
- (4) The addressable rrMM patients for Y150 are those who are undergoing 2nd or later-lines of treatment for rrMM. In this table, the number of addressable patients (60.4 thousand) is arrived by multiply the rrMM Prevalence by the Treatment Rate and 2nd-Line Treatment Rate (84.4 thousand * 85.8% * 83.5%).

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The market size of MM therapies grew from RMB2.2 billion in 2017 to RMB7.4 billion in 2021, representing a CAGR of 35.2%. It is predicted that the number will continue to grow, and reach RMB14.8 billion in 2025, RMB22.8 billion in 2030, with CAGR of 19.0% and 9.1% from 2021 to 2025 and from 2025 to 2030, respectively.

China’s Market Size of MM Therapies, 2017-2030E



Source: Annual Reports of Listed Medical Companies, NCCR, MOHRSS, Frost & Sullivan Analysis

Competitive Landscape of CD38 Targeted Therapies

CD38 is an emerging target for the treatment of MM. There are multiple CD38 targeted antibodies being developed for the treatment of MM. The following table sets forth the details of marketed CD38 targeted antibody drugs or fusion proteins for the treatment of MM globally (excluding China) and in China as of the Latest Practicable Date:

Global Marketed Drugs								
Product	Drug Name	Developer	Target	Drug Type	Indication	Approval Date	Price (USD)	Combination Therapy
DARZALEX FASPRO	Daratumumab	Genmab A/S	CD38	mAb	MM	May 1, 2020	1800mg/15ml 15ml: 9,611	Combination with lenalidomide/ bortezomib and dexamethasone
SARCLISA	Isatuximab	Sanofi	CD38	mAb	MM	March 2, 2020	20mg/ml 5ml: 783	Combination with carfilzomib and dexamethasone
DARZALEX	Daratumumab	Genmab A/S	CD38	mAb	MM	November 16, 2015	20mg/ml 5ml: 713	Combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Global Marketed Drugs								
Product	Drug Name	Developer	Target	Drug Type	Indications	Approval Date	Price (RMB) in 2021	Combination Therapy
DARZALEX	Daretuzumab Injection	Janssen-Cilag International NV	CD38	mAb	MM	July 4, 2019	100mg: 2,358	Combination with lenalidomide/ bortezomib and dexamethasone

Source: NMPA, CDE, FDA, NKEXnews, Annual Reports of Listed Medical Companies, NRDL, Clinical Trials, Frost & Sullivan

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As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively.

The development of CD38 targeted BsAb is still at its emerging stage. However, there is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed “– Global and China Antibody Drug Market – Overview” in this section. The following table sets forth the competitive landscape of CD38 targeted BsAb for the treatment of MM globally as of the Latest Practicable Date:

Global Pipeline							
Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date ⁽¹⁾
Y150	the Company	CD38, CD3	BsAb	Multiple myeloma	Global	FDA IND Approval	\
					China	I	2021/5/28
ISB 1442	Ichnos Sciences SA	CD38, CD47	BsAb	Multiple myeloma	Global	I/II	2022/6/22
ISB 1342	Ichnos Sciences SA, Glenmark Pharmaceuticals S.A.	CD38, CD3	BsAb	Multiple myeloma	Global	I	2017/10/13
SG2501	Hangzhou Sumgen Biotech Co., Ltd.	CD38, CD47	BsAb	Relapsed or Refractory Hematological Malignancies and Lymphoma	Global	I	2022/3/24

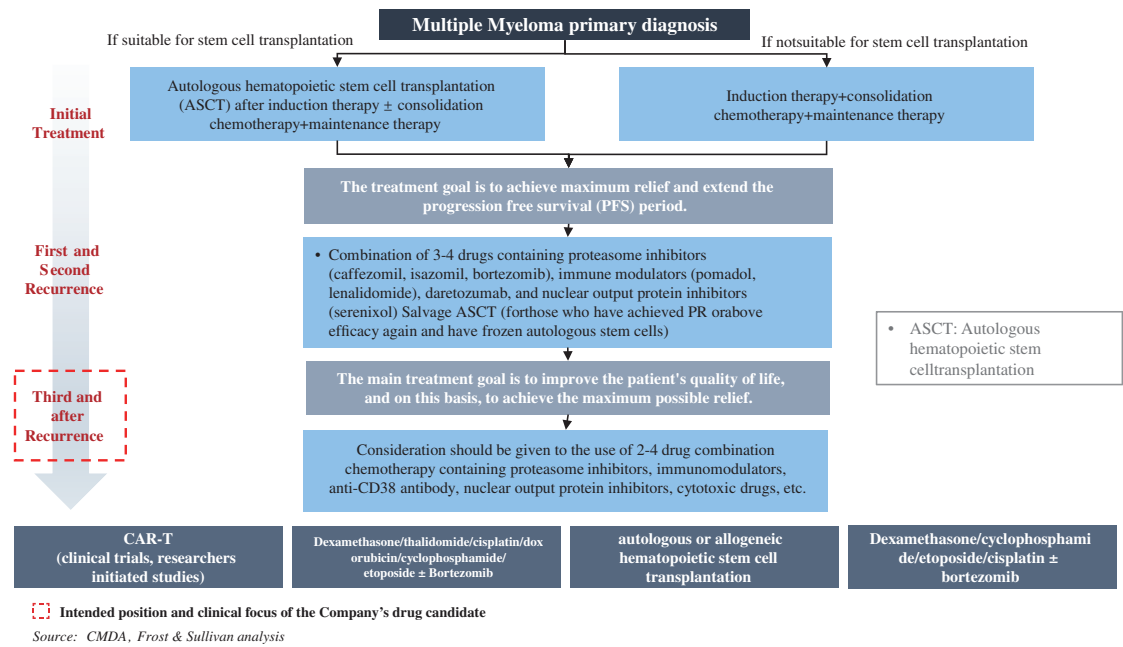
Source: NMPA, CDE, ClinicalTrials.gov, FDA, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

The development of CD38 targeted therapy in combination with other drugs represents a validated therapeutic strategy. For instance, the results of the Phase I/II clinical trial of daratumumab, a marketed CD38 targeted drug, for rrMM treatment, indicated the efficacy of monotherapy in patients with heavily pretreated rrMM. Moreover, in a Phase I/II clinical trial and a Phase III clinical trial of the combination therapy involving CD38 targeted drugs (daratumumab) for rrMM treatment, daratumumab in combination with lenalidomide/dexamethasone showed encouraging efficacy in patients with rrMM. The results of such clinical trials also indicated that the combination of CD38 targeted drugs and lenalidomide may have better efficacy than CD38 targeted monotherapies, evidencing the potentials of CD38 targeted BsAbs, including Y150, in combination therapies for rrMM treatment.

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Treatment Paradigm for MM in China



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The following table sets forth features and limitations of treatments for rMM patients.

Major Treatments	Features	Limitations
Anti-CD38 Antibody+PIs + IMiDs	Studies showed the combination of daratumumab, lenalidomide, and dexamethasone showed better efficacy than other regimens in terms of nonresponse rate (NRR), time to progression (TTP), progression-free survival (PFS)	Infusion-related reactions still haven't been solved and more combined strategies are needed to maximize the strength of CD38 in the treatment of rMM. CD38 antibodies do not clear small residual lesions (MRD) and patients remain vulnerable to relapse and drug resistance.
PIs + Chemotherapy	The proteasome degrades proteins through the ubiquitin-proteasome system (UPS). Due to the genetic instability and rapid proliferation of MM cells, it relies more on the proteasome to remove misfolded or damaged proteins .	Different proteasome inhibitors (PIs) have different mechanisms of action, and also cause different adverse drug reactions in the process of anti-MM
IMiDs + Chemotherapy	IMiD has direct and indirect anti-tumor effects. On the one hand, IMiD can directly induce cell cycle arrest and apoptosis in myeloma cells; on the other hand, immunomodulatory drugs (IMiDs)'s indirect anti-myeloma activity is through changing the It is mainly related to IMiD inhibiting the expression of surface adhesion molecules on MM cells and bone marrow stromal cells (BMSCs) and inhibiting angiogenesis	With the popularization of IMiD in the treatment of MM, its drug resistance has gradually emerged, which makes the treatment of MM encounter difficulties again.
CAR-T	MM is difficult to cure, and recurrence and refractory remain major problems in MM treatment. Multiple clinical studies have shown that CAR-T therapy targeting B-cell maturation antigen (BCMA) improves remission rates in relapsed refractory MM	At present, autologous T cell "modification" is the main technology of CAR-T, that is, the patient's own T cells are extracted for gene editing and then infused. The treatment process is notably time-consuming and expensive, but also has a high risk of CRS. In addition, the patients often receive a multiple of treatments in the early stage, and their immune cells are severely weakened, which limits its clinical efficacy.
BCMA x CD3 BsAb	Antibodies against cellular adhesion molecules such as B Cell Maturation Antigen (BCMA), such as Teclistamab, can serve as a bridge between T cells and Plasma tumor cells expressing BCMA, leading to T cell activation and subsequent killing of the tumor cells. Teclistamab can be utilized to treat patients with rMM who have not responded to CD38, PIs, and IMiDs treatments.	Teclistamab was approved by the FDA based on a Phase II clinical trial involving only 110 patients. However, further clinical efficacy data and safety profiles are required to fully establish its efficacy and safety in treating multiple myeloma.

Intended position and clinical focus of the Company's drug candidate

Abbreviations: PIs refers to Protease inhibitor, a class of compounds that inhibit the activity of protein kinases; IMiD refers to immunomodulatory drug, drug that regulate cellular and humoral immune functions and can enhance immune function, such as Lenalidomide.

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Future Trends and Needs of MM Treatment

The future trends of MM treatment mainly include: (a) strategies that focus more on the continued improvement in long-term outcomes of emerging pipeline therapies, along with the combination of newer agents with establish regimens; (b) developing indicators that can predict different treatment responses and different prognoses of patients, since MM is incurable, patients will eventually relapse and require further treatment, and the discovery of indicators that can distinguish patients with good prognosis from patients with poor prognosis will facilitate the guidance of treatment options for patients; and (c) the clinical focus on overcoming drug resistance, which the basis for disease relapse in most patients.

Despite of the continuous development of therapies to address the demands of MM patients, there remain medical demands, including the following: (a) MM remains incurable and patients will eventually relapse and succumb to their disease; therefore, patients may require continuous treatment in order to manage MM, and new classes of therapy with novel mechanisms of action are required for patients that relapse or are refractory to the current classes of drugs; and (b) the significant cost of treatment for MM patients lead to strong demands for more cost-effective therapies.

HER2 × CD3 Targeted BsAb

Mechanisms of HER2 × CD3 Targeted BsAbs

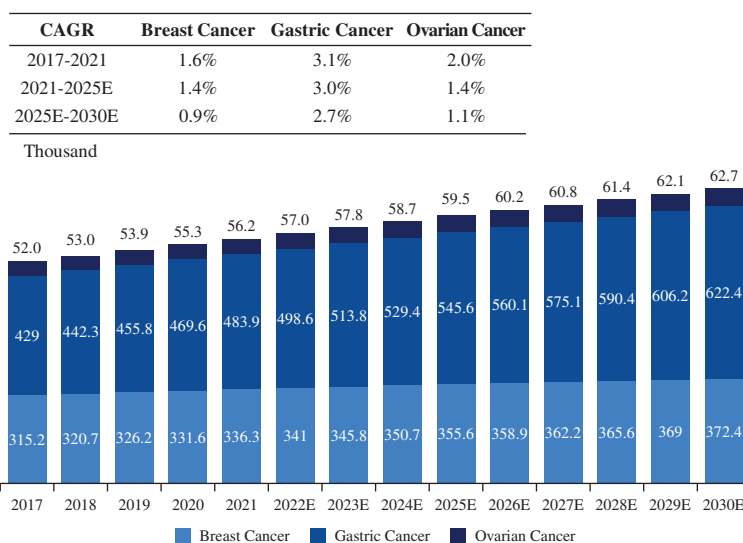
HER2 is a ligand-orphan receptor which is expressed in many human tumors, especially in breast cancers. An anti-HER2 × CD3 BsAb recruits and redirects T cells to HER2+ tumor cells through binding to CD3 and HER2, and further activates T cells to kill the tumor cells. Additionally, the anti-HER2 × anti-CD3 BsAb prevents the dimerization of the receptor HER2, increases endocytic destruction of the receptor, and inhibits shedding of the extracellular domain of HER2.

Market of HER2 Targeted BsAb

HER2 is highly expressive in many types of cancers, including breast cancer, gastric cancer and ovarian cancer. The incidence of breast cancer, gastric cancer and ovarian cancer in China reached 336.3 thousand, 483.9 thousand and 56.2 thousand in 2021, respectively, and is expected to reach 355.6 thousand, 545.6 thousand and 59.5 thousand in 2025 and 372.4 thousand, 622.4 thousand and 62.7 thousand in 2030, respectively. In particular, the annual incidence of late-stage HER2 positive gastric cancer and late-stage HER2 positive breast cancer are expected to reach 109.5 thousand and 49.9 thousand, respectively, in China by 2030.

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China’s Incidence of Breast Cancer, Gastric Cancer and Ovarian Cancer, 2017-2030E



Source: NCCR, Frost & Sullivan Analysis

(1) the epidemiological data for cancer in this stacked graph are non-accumulative

According to Frost & Sullivan, the addressable breast cancer patients of M802 in China in 2030 is estimated to be 13.6 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable Breast Cancer patients of M802 in China	Unit	2030E
Breast Cancer Incidence ⁽¹⁾	Thousand	372.4
Total Late Stage HER2+ Breast Cancer Patients ⁽²⁾	Thousand	49.9
Treatment Rate ⁽³⁾	%	95.0
2nd-line Treatment Rate ⁽⁴⁾	%	60.0
3rd-line Treatment Rate ⁽⁵⁾	%	48.0
Addressable patients⁽⁶⁾	Thousand	13.6

Notes:

- (1) The source of breast cancer incidences in China is National Cancer Registry and International Agency for Research on Cancer.
- (2) The total number of late-stage HER2+ breast cancer patients are calculated by taking the breast cancer incidence and multiplying it by the proportion of late-stage breast cancer patients (52.8%, according to published research paper). Then, add the number of non-late-stage breast cancer patients multiplied by the proportion of non-late-stage breast cancer patients who progress to late-stage breast cancer (30%, according to the China Guidelines for Standardized Diagnosis and Treatment of Advanced Breast Cancer). Finally, multiply the result by the proportion of HER2+ breast cancer patients (20%, according to published research paper). In summary, the 49.9 thousand is derived from the below formulation: (372.4 thousand * 52.8% + (372.4 thousand * (1-52.8%) * 30%)) * 20%.

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- (3) Nearly all patients are willing to undergo treatment when they are first diagnosed with breast cancer, with a treatment rate of around 95%.
- (4) The treatment rate for the 1st line is relatively high, while the treatment rate for the subsequent lines of treatment is comparatively lower.
- (5) The 3rd-line treatment rate for breast cancer is expected to be around 48% by 2030.
- (6) The addressable breast cancer patients for M802 are those who are undergoing 3rd-line treatment or later lines of treatment for HER2+ breast cancer. In this table, the number of addressable patients (13.6 thousand) is arrived by multiply the Total Late Stage HER2+ Breast Cancer Patients by the Treatment Rate, 2nd-line Treatment Rate and 3rd-line Treatment Rate (49.9 thousand * 95.0% * 60.0% * 48.0%).

According to Frost & Sullivan, the addressable gastric cancer patients of M802 in China in 2030 is estimated to be 39.4 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable Gastric Cancer Patients of M802 in China	Unit	2030E
Gastric Cancer Incidence ⁽¹⁾	Thousand	622.4
Total Late Stage HER2+ Gastric Cancer Patients ⁽²⁾	Thousand	109.5
Treatment Rate ⁽³⁾	%	95.0
2nd-line Treatment Rate ⁽⁴⁾	%	62.1
3rd-line Treatment Rate ⁽⁵⁾	%	61.0
Addressable patients⁽⁶⁾	Thousand	39.4

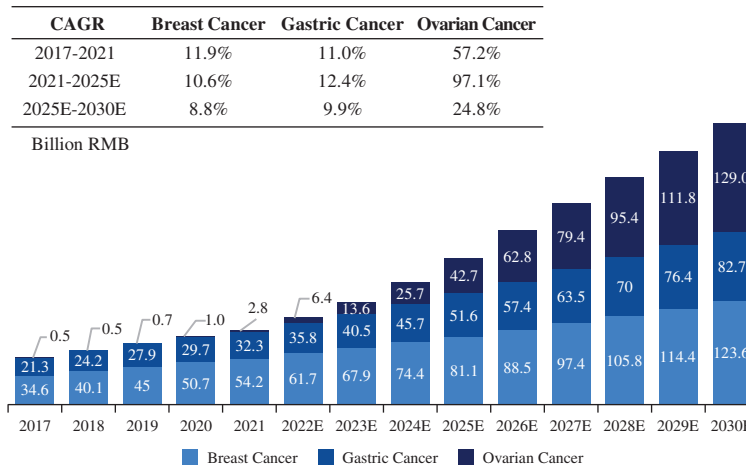
Notes:

- (1) The source of gastric cancer incidences in China is National Cancer Registry and International Agency for Research on Cancer.
- (2) The total number of late-stage HER2+ gastric cancer patients are calculated by taking the gastric cancer incidence and multiplying it by the proportion of late-stage gastric cancer patients (80%, according to published research paper). Then, add the number of non-late-stage gastric cancer patients multiplied by the proportion of non-late-stage gastric cancer patients who progress to late-stage gastric cancer (40%, according to published research paper). Finally, multiply the result by the proportion of HER2+ gastric cancer patients (20%, according to published research papers). In summary, the 109.5 thousand is derived from the below formulation: (622.4 thousand * 80% + (622.4 thousand * (1-80%) * 40%)) * 20%.
- (3) Nearly all patients are willing to undergo treatment when they are first diagnosed with gastric cancer, with a treatment rate of around 95%.
- (4) The treatment rate for the 1st line is relatively high, while the treatment rate for the subsequent lines of treatment is comparatively lower.
- (5) According to published research paper, the 3rd-line treatment rate for gastric cancer is approximately 61%.
- (6) The addressable gastric cancer patients for M802 are those who are undergoing 3rd-line treatment or later lines of treatment for HER2+ gastric cancer. In this table, the number of addressable patients (39.4 thousand) is arrived by multiply the Total Late Stage HER2+ Gastric Cancer Patients by the Treatment Rate, 2nd-line Treatment Rate and 3rd-line Treatment Rate (109.5 * 95.0% * 62.1% * 61.0%)

The market size of breast cancer, gastric cancer and ovarian cancer in China reached RMB54.2 billion, RMB32.3 billion and RMB2.8 billion in 2021, respectively, and is expected to reach 81.1 thousand, 51.6 thousand and 42.7 thousand in 2025 and RMB123.6 billion, 82.7 billion and RMB129.0 billion in 2030, respectively.

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China Market Size of Breast Cancer, Gastric Cancer and Ovarian Cancer, 2017-2030E



Source: Annual Reports of Listed Medical Companies, NCCR, MOHRSS, Frost & Sullivan Analysis

(1) the market size data for cancer in this stacked graph are non-accumulative

Competitive Landscape of HER2 Targeted Therapies

HER2 is an emerging target for cancer treatment. As of the Latest Practicable Date, there were 13 HER2 targeted antibody drugs approved for the treatment of HER2-positive solid tumors globally (excluding China), at price ranging from US\$1,284 per dose to US\$8,929 per dose, and five approved in China. As of the same date, there were 141 and 56 HER2 targeted antibody drug candidates or fusion proteins for the treatment of HER2-positive solid tumors under clinical development globally (excluding China) and in China, respectively. The following table sets forth the details of marketed HER2 targeted antibody drugs or fusion proteins for the treatment of HER2-positive solid tumors in China as of the Latest Practicable Date:

China Marketed Drugs								
Product	Drug Name	Developer	Target	Drug Type	Indications	Approval Date	Price (RMB) in 2021	Combination Therapy
Herceptin	Trastuzumab for Injection	Roche Pharma	HER2	mAb	Gastric Cancer, Breast Cancer, and HER2-positive Breast Cancer	October 22, 2021	440mg: 5,500	Combination with trastuzumab
Zercepac	Trastuzumab Injection	Shanghai Henlius Biotech, Inc.	HER2	mAb	Gastric Cancer, Breast Cancer, and HER2-positive Breast Cancer	August 12, 2020	150mg: 1,688	Combination with pertuzumab
Cipterbin	Inetetamab for Injection	Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd.	HER2	mAb	HER2-positive Breast Cancer	June 17, 2020	50mg: 590	Combination with chemotherapy
Kadcyla	Trastuzumab Emtansine for Injection	Roche Pharma (Schweiz) AG	HER2	ADC	HER2-positive Breast Cancer	January 21, 2020	100mg: 19,282	Purple shingles in combination with trastuzumab-based neoadjuvant therapy
Perjeta	Pertuzumab Injection	Roche Pharma (Schweiz) AG	HER2	mAb	HER2-positive Breast Cancer	December 17, 2018	420mg: 4,955	Combination with pertuzumab
Enhertu	Dextrastuzumab for injection	DAIICHI SANKYO COMPANY	HER2	ADC	HER2 positive breast cancer	February 21, 2023	100mg: 9,432	NA
HS022	Trastuzumab for injection	Hisun Biopharmaceutical Co., Ltd.	HER2	mab	Breast cancer, Gastric cancer	February 28, 2023	150mg:1,588	Combination with vinorelbine
RC48	Disitamab Vedotin for injection	Remegen Co., Ltd.	HER2	ADC	Urothelial carcinoma, gastric carcinoma, gastroesophageal junction adenocarcinoma	June 8, 2021	60mg:13,500	Combination with toripalimab

Source: NMPA, CDE, NKEXnews, Annual Reports of Listed Medical Companies, NRDL, Frost & Sullivan

INDUSTRY OVERVIEW

As of the Latest Practicable Date, there were ten HER2-targeted BsAb pipelines under clinical development globally (excluding China), and 13 HER2-targeted BsAb pipelines under clinical development in China. The development of HER2 × CD3 BsAbs represents an emerging trend. As of the Latest Practicable Date, there were four HER2 × CD3 BsAbs under clinical development globally, including M802, RG6194, EX 101 Injection and AMX 818, as illustrated in the table below:

Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date ⁽¹⁾
Runimotamab (RG6194)	Genentech, Inc.	HER2, CD3	BsAb	Advanced or Metastatic HER2-Expressing Cancers	Global	I	2018/2/27
M802	the Company	HER2, CD3	BsAb	Advanced HER2-Expressing Solid Tumors	Global China	FDA IND Approval I	\ 2018/7/26
EX101 Injection	Guangzhou AI Simai Biomedical Technology Co., Ltd.	HER2, CD3	BsAb	HER2-positive advanced solid tumors	China	I	2021/09/15
AMX 818	Amunix Pharmaceuticals	HER2, CD3	BsAb	Locally Advanced or Metastatic HER2-Expressing Cancers	Global	I	2022/5/2

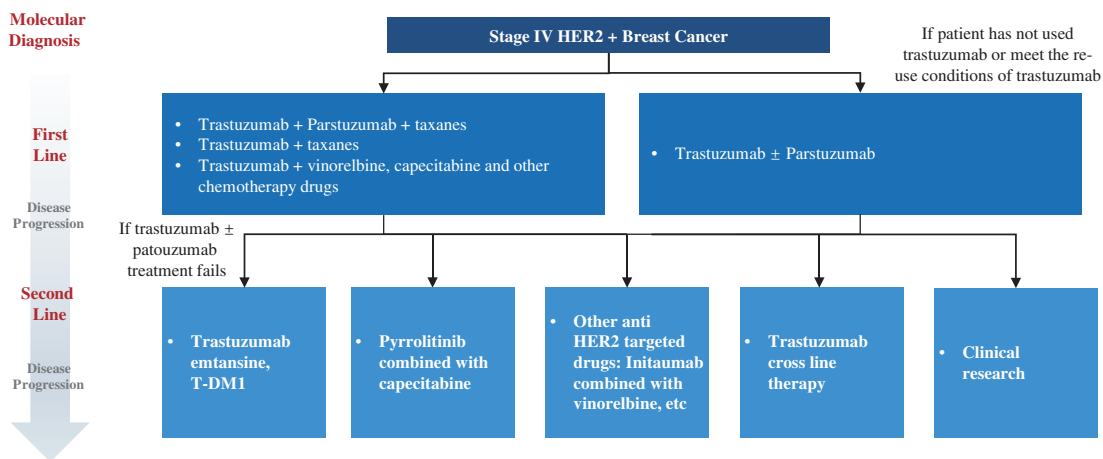
Source: CDE, Frost & Sullivan Analysis

- (1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

The development of HER2 x CD3 BsAb represents a validated therapeutic strategy. For instance, the results of Phase I clinical trial of Ertumaxomab, a HER2 × CD3 targeted BsAb, for metastatic breast cancer showed encouraging anti-tumor efficacy, evidencing the therapeutic potential of HER2 × CD3 targeted BsAb, including M802, in treating HER2-positive solid tumors.

Treatment Paradigm for Breast Cancer in China

M802 is an innovative therapy intended for the treatment of HER2+ late-stage breast cancer patients in the third-line and beyond where there is no treatment guideline. M802 is therefore not currently included in the treatment paradigm below.



Source: NHC, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

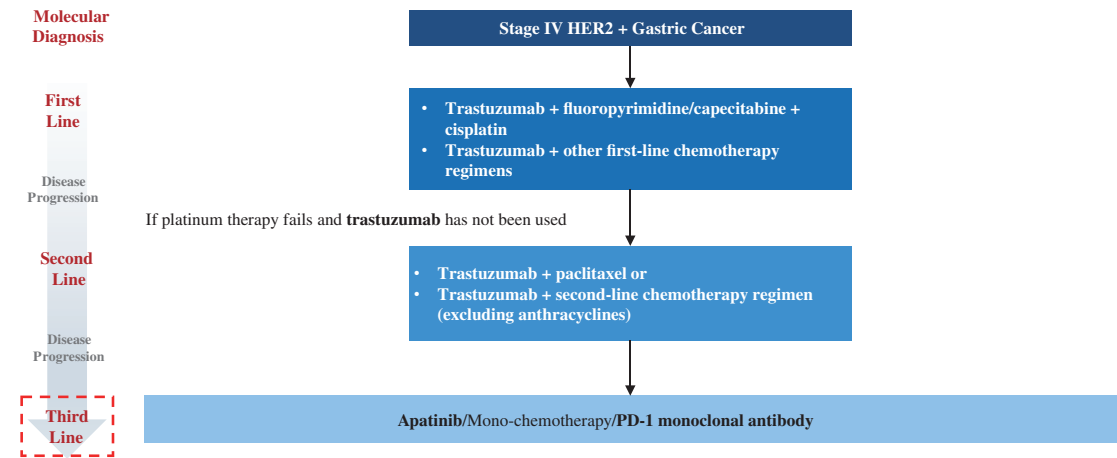
The following table sets forth features and limitations of 2L/2L+ treatments for late stage HER2+ breast cancer patients.

Treatment	Features	Limitations
Chemotherapy + Anti-HER2 antibodies	1. significantly improved the median progression-free survival (PFS) 2. These antibodies mainly inhibit tumor growth by blocking the signaling pathways associated with tumor cell growth, or killing tumor cells through antibody-mediated effects such as ADC.	A greater proportion of patients with low HER2 expression do not have good access to HER2-targeted therapies; a higher proportion of patients with high HER2 expression still do not respond to HER2-targeted therapies; HER2-targeted therapies of the same mechanism may gain the same resistance after a period of time.
Chemotherapy + Anti-HER2 antibodies+TKI	1. Higher specificity than monotherapy 2. Reducing drug resistance using the different anti-tumor mechanisms between antibodies and TKI.	Some patients may not tolerate combination therapy. Adverse events(AEs) possibly happen. In addition, now it is mainly effective for high expression of HER2 and more than half of patients with high expression of HER2 are still ineffective. Drug resistance may develop quickly after treatment, and other new mechanisms to improve the efficacy of this therapy still need to be developed.
Chemotherapy + TKI	Oral dosage forms are convenient to use, and help to improve patient compliance. Small molecule drugs can cross the blood-brain barrier, which shows excellent efficacy in patients with brain metastases	Requires long-term medication, which affects the patient's quality of life. Resistance develops relatively quickly after treatment, and other new mechanisms of therapy are still needed.
Anti-HER2 ADC	ADC links a humanized monoclonal antibody targeting a specific antigen on the surface of tumor cells with cytotoxic agent into cancer cells, reducing systemic exposure of the cytotoxic agents compared to the conventional chemotherapy.	The cytotoxicity causes off-target toxicity of ADC or other chemotherapy-associated AEs (adverse events). Resistance can also develop relatively quickly after treatment.

Intended position and clinical focus of the Company's drug candidate

INDUSTRY OVERVIEW

Treatment Paradigm for Gastric Cancer in China



❑ Intended position and clinical focus of the Company's drug candidate
Source: National Health Commission of the People's Republic of China, Frost & Sullivan Analysis

M802 is intended for the treatment of HER2+ late-stage gastric cancer patients in the third-line and beyond where there is no treatment guideline. M802 is therefore not currently included in the treatment paradigm above.

INDUSTRY OVERVIEW

The following table sets forth features and limitations of 2L/2L+ treatment for late stage HER2+ gastric cancer patients.

Treatment	Features	Limitations
Anti-VEGF antibody (e.g. Ramucirumab)+chemo (e.g. paclitaxel)	Improved survival prognosis foradvanced gastric cancer indicating overall survival (OS) and progression-free survival (PFS)	Limited efficacy. Ramucirumab not available in China at present. Treatment-related AEs (TRAEs) of any grade that occurred in at least 10% of the patients.
TKI (e.g.Apatinib)	It is efficient for patients with gastric cancer who have failed second-line chemotherapy or higher. Study showed that apatinib mesylate treatment prolonged median PFS and improved disease control rate	Limited efficacy. Combination therapy with chemotherapy does not improve its performance in the treatment of end-stage gastric cancer
Anti-PD-1 antibodies (e.g.Pembrolizumab)	A good performance as a 3L treatment in patients with progressive or metastatic gastric cancer.	Limited efficacy. Only good for 3L/3L+ treatment of patients whose previous treatment didn't include PD-1/PD-L1 monoclonal antibody
Anti-HER2 antibody (e.g. Trastuzumab)+chemo (e.g. taxol, anthracyclines)**	Several studies have shown that HER2 positivity was associated with poor prognosis and clinical characteristics in gastric cancer and anti-HER2 drugs are recommended for the first-line treatment in guidelines.	A greater proportion of patients with low HER2 expression do not have a good access to HER2-targeted therapies, a higher proportion of patients with high HER2 expression still do not respond to HER2-targeted therapies, and HER2-targeted therapies of the same mechanism may gain the same resistant after a period of time

Intended position and clinical focus of the Company's drug candidate

INDUSTRY OVERVIEW

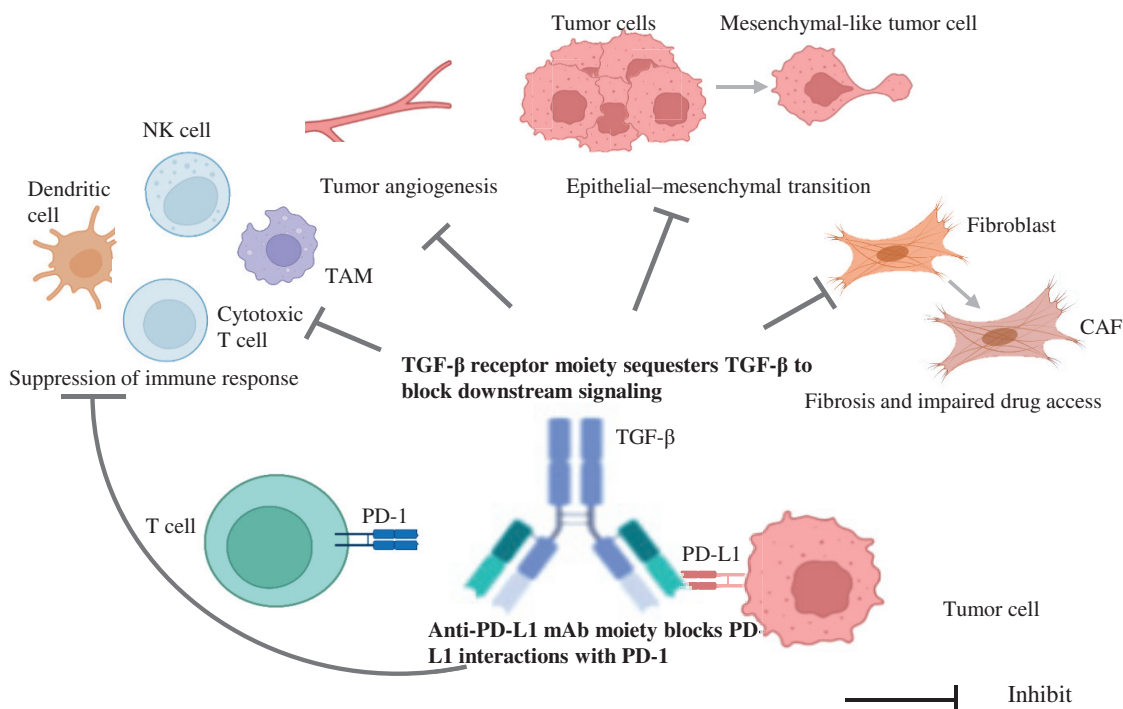
PD-1/PD-L1 × TGF- β TARGETED DRUGS MARKET

Anti-PD-1/PD-L1 Therapy and TGF- β Pathway

Programmed Death-1 (PD-1) is a critical immune checkout receptor expressed on T cells upon activation. Engagement of PD-1 by its ligands, PD-L1 and PD-L2, transduces a signal that inhibits T cell proliferation, cytokine production, and cytolytic function. The normal function of PD-1 is to modulate T cell-mediated immune response in order to prevent the immune system from attacking normal healthy tissue in the body. However, this safeguarding mechanism is often exploited by cancer cells to evade immune surveillance. Many solid tumor cells produce a large amount of PD-L1 to circumvent T cell assaults.

The transforming growth factor- β (TGF- β) is a family of structurally related proteins that has a dual action in cancer as a tumor suppressor and a tumor promoter. It can induce cellular growth arrest and apoptosis at the early stage of cancer as a tumor suppressor. During later stages of tumor progression, it acts as a tumor promoter and induce migration and stimulate epithelial to mesenchymal transition.

TGF- β can promote PD-1/PD-L1 resistance by converting conventional T cells to immune-suppressive T-reg cells and increasing the survival of myeloid progenitors that differentiate to potent myeloid-derived suppressor cells (MDSCs). Both of these processes result in increased expression of TGF- β while MDSCs express PD-L1 and drive T-reg cell differentiation. By simultaneously inhibiting the PD-1/PD-L1 axis and the TGF- β signaling pathways, a PD-1/PD-L1 × TGF- β targeted BsAb could restore the dysregulated anti-tumor immunity of cancer patients and establish an immuno-supportive tumor microenvironment. The diagram below illustrates the mechanism of action of PD-1/PD-L1 × TGF- β targeted BsAbs.



Source: *Journal for ImmunoTherapy of Cancer*, 2022, 10(12): e005543., *Molecular oncology*, 2022, 16(11): 2117-2134., *Antibody Therapeutics*, 2020, 3(2): 126-145., *ADMET and DMPK*, 2017, 5(3): 159-172., *Frost & Sullivan Analysis*

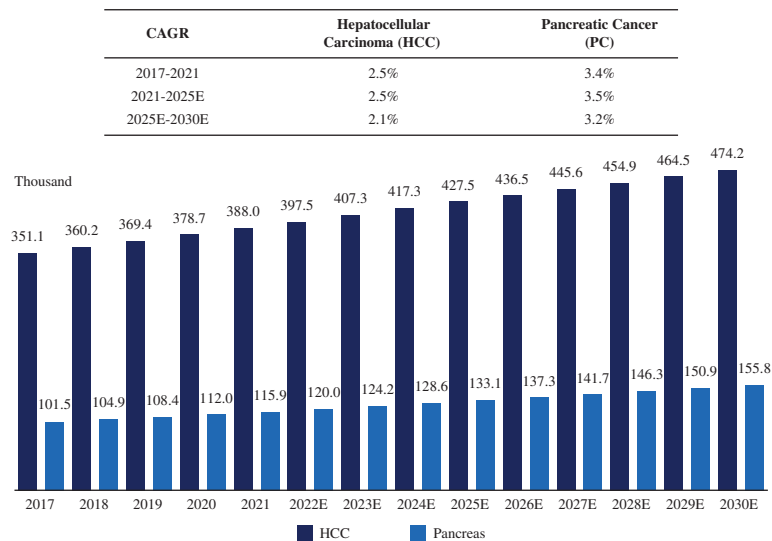
Abbreviations: TAM refers to Tumor-associated macrophage; CAF refers to Cancer-associated fibroblast.

INDUSTRY OVERVIEW

China’s Market of PD-1/PD-L1 × TGF-β Targeted Drugs

According to Frost & Sullivan, anti-PD-1/PD-L1 antibodies have robust and durable anti-cancer activities across several solid cancers, such as pancreatic cancer and HCC. From 2017 to 2021, the incidence of HCC had grown from 351.1 thousand in 2017 to 388.0 thousand in 2021, representing a CAGR of 2.5%. It is expected that the the incidence of HCC will increase to 427.5 thousand in 2025 and 474.2 thousand in 2030, at a CAGR of 2.5% from 2021 to 2025, and 2.1% from 2025 to 2030. In particular, the annual incidence of late-stage HCC is expected to reach 237.1 thousand in China by 2030. The incidence of pancreatic cancer in China grew from 101.5 thousand in 2017 to 115.9 thousand in 2021, representing a CAGR of 3.4%. It is expected that the prevalence will increase to 133.1 thousand in 2025, and 155.8 thousand in 2030, at a CAGR of 3.5% from 2021 to 2025, and 3.2% from 2025 to 2030. In particular, the annual incidence of late-stage PC is expected to reach 124.6 thousand in China in 2030.

China’s Incidence of HCC and Pancreatic Cancer, 2017-2030E



Source: NCCR, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

According to Frost & Sullivan, the addressable HCC patients of Y101D in China in 2030 is estimated to be 222.9 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable HCC Patients of Y101D in China	Unit	2030E
Incidence of HCC ⁽¹⁾	Thousand	474.2
Late Stage HCC Patients ⁽²⁾	Thousand	237.1
1st-line Treatment Rate ⁽³⁾	%	94.0
Addressable Patients⁽⁴⁾	Thousand	222.9

Notes:

- (1) The source of HCC incidences in China is Globocan.
- (2) According to published research papers, approximately 50% of HCC patients are late stage patients. The number of Late Stage HCC Patients is derived from multiple the Incidence of HCC (474.2 thousand) by 50%.
- (3) Approximately 94% of late-stage HCC patients take treatment first time they are diagnosed with HCC.
- (4) Addressable patients mean late stage HCC patients who receive 1st-line treatment are addressable patients for Y101D. In this table, the number of addressable patients (222.9 thousand) is arrived by multiply the Incidence of HCC by the 1st-line Treatment Rate (237.1 thousand * 94.0%).

According to Frost & Sullivan, the addressable pancreatic cancer patients of Y101D in China in 2030 is estimated to be 104.7 thousand. The table below sets forth the basis and assumption of the estimation of Frost & Sullivan.

Addressable Pancreatic Cancer Patients of Y101D in China	Unit	2030E
Incidence of Pancreatic Cancer ⁽¹⁾	Thousand	155.8
Late Stage Pancreatic Cancer Patients ⁽²⁾	Thousand	124.6
1st-line Treatment Rate ⁽³⁾	%	84.0
Addressable Patients⁽⁴⁾	Thousand	104.7

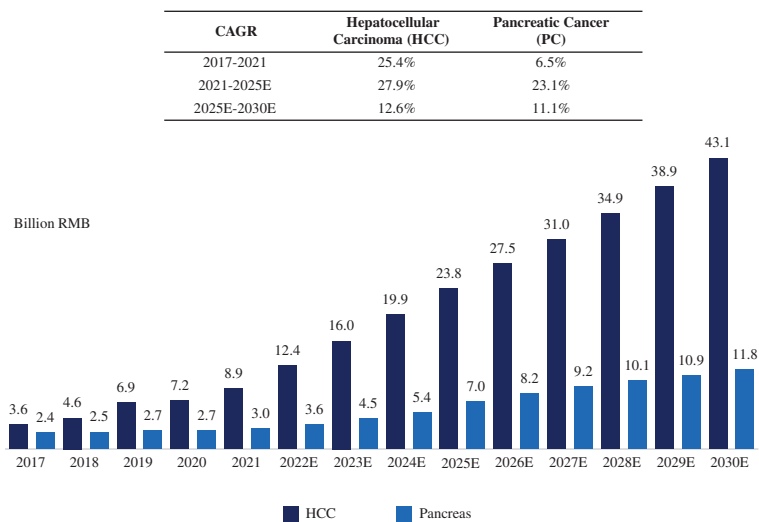
Notes:

- (1) The source of pancreatic cancer incidences in China is Globocan.
- (2) According to published research papers, approximately 80% of pancreatic cancer patients are late-stage patients beyond the stage of surgical resection when diagnosed. The number of Late Stage Pancreatic Cancer Patients is derived from multiple the Incidence of Pancreatic Cancer (155.8 thousand) by 80%.
- (3) The first-line treatment rate of late-stage pancreatic cancer patients is approximately 84%.
- (4) Addressable patients mean late-stage pancreatic cancer patients who receive 1st-line treatment are addressable patients for Y101D. In this table, the number of addressable patients (104.7 thousand) is arrived by multiply the Incidence of Pancreatic Cancer by the 1st-line Treatment Rate (124.6 thousand * 84.0%).

INDUSTRY OVERVIEW

The market size of HCC in China has grown from RMB3.6 billion in 2017 to RMB8.9 billion in 2021, representing a CAGR of 25.4%. It is expected that the market size will increase to RMB23.8 billion in 2025, and RMB43.1 billion in 2030, at a CAGR of 27.9% and 12.6%, from 2021 to 2025 and from 2025 to 2030, respectively. The market size of pancreatic cancer in China has grown from RMB2.4 billion in 2017 to RMB3.0 billion in 2021, representing a CAGR of 6.5%. It is expected that the market size will increase to RMB7.0 billion in 2025, and RMB11.8 billion in 2030, at a CAGR of 23.1% and 11.1%, from 2021 to 2025 and from 2025 to 2030, respectively. The chart below illustrates China’s market size of HCC and pancreatic cancer for the periods indicated.

China’s Market Size of HCC and Pancreatic Cancer, 2017-2030E



Source: Annual Reports of Listed Medical Companies, NCCR, MOHRSS, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Competitive Landscape of PD-1/PD-L1 × TGF-β Targeted Drugs

The PD-1/PD-L1-based pathway is of great value in immunotherapy of cancer and has become an important immune checkpoint during recent years. As of the Latest Practicable Date, there were 23 PD-1/PD-L1 targeted antibody drugs or fusion proteins approved for the treatment of solid tumors globally (excluding China), at price ranging from US\$7,450 per dose to US\$10,128 per dose, and 13 approved in China, at price ranging from RMB1,075 per dose to RMB32,800 per dose. These marketed products have proved the efficacy of PD-1/PD-L1 targeted pathway in tumor treatment. PD-1/PD-L1 targeted antibody drugs or fusion proteins can also be used in combination with other drugs, such as Bevacizumab, Lenvatinib, for the treatment of solid tumors.

More PD-1/PD-L1 targeted drug candidates for solid tumor treatment are under development. As of the Latest Practicable Date, there were 65 and 55 PD-1/PD-L1 targeted antibody drug candidates or fusion proteins for the treatment of solid tumors under clinical development globally (excluding China) and in China, respectively.

Considerable efforts have also been directed toward the studies of the TGF-β signaling pathway. As of the Latest Practicable Date, there was no TGF-β targeted antibody drug or fusion protein approved for the treatment of solid tumors globally. As of the same date, there were 20 and 16 TGF-β targeted antibody drugs or fusion proteins for the treatment of solid tumors under clinical development globally (excluding China) and in China, respectively.

Meanwhile, no PD-1/PD-L1 × TGF-β BsAb drug is marketed either globally or in China. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

INDUSTRY OVERVIEW

The following table summarizes the status of PD-1/PD-L1 × TGF-β pipelines under clinical trials in China as of the Latest Practicable Date:

China Pipeline						
Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase	First Posted Date ⁽¹⁾
M7824	Merck & Co., Inc.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor (including, NSCLC, cholangiocarcinoma, cervical cancer)	III	2022/4/21
SHR-1701	Jiangsu Hengrui Medicine Co Ltd, Shanghai Hengrui Pharmaceutical Co Ltd, Suzhou Suncadia Biopharmaceuticals Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor (including, NSCLC, cervical cancer, gastric cancer)	III	2021/11/17
PM-8001	Biotheus Inc	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	II	2020/6/24
TQB2858	Nanjing Jun Xin Pharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2021/3/25
JS-201	Shanghai Junshi Biosciences Co Ltd	PD-1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/5/21
QLS31901	Qilu Pharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/6/2
Y101D	the Company	PD-L1, TGF-β	BsAb	Metastatic or locally advanced solid tumors; HCC; PC	Ib/II	2022/12/05
BR102	Hisun Biopharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2021/9/13
LBL-015	Nanjing Leads Biolabs Co., Ltd.	PD-1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/9/22
TQB-2868	Nanjing Shunxin Pharmaceuticals Co, Ltd of Chiatai Tianqing Pharmaceutical Group	PD-1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2022/2/14
BJ-005	Boji Biomedical Technology (Hangzhou) Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor; advanced lymphadenoma	I	2022/3/9
GT-90008	Kintor Pharmaceutical (Guangdong) Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/5/31
TST-005	Mabspace Biosciences (Suzhou) Co, Limited	PD-L1, TGF-β	Fusion Protein	Metastatic or locally advanced solid tumors (e.g. HPV positive, NSCLC)	I	2022/7/1
HB-0028	Huabo Biopharm Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/8/9
LY01019	Shandong Boan Biotechnology Co. Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/8/30
6MW3511	Mabwell (Shanghai) Bioscience Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/9/1

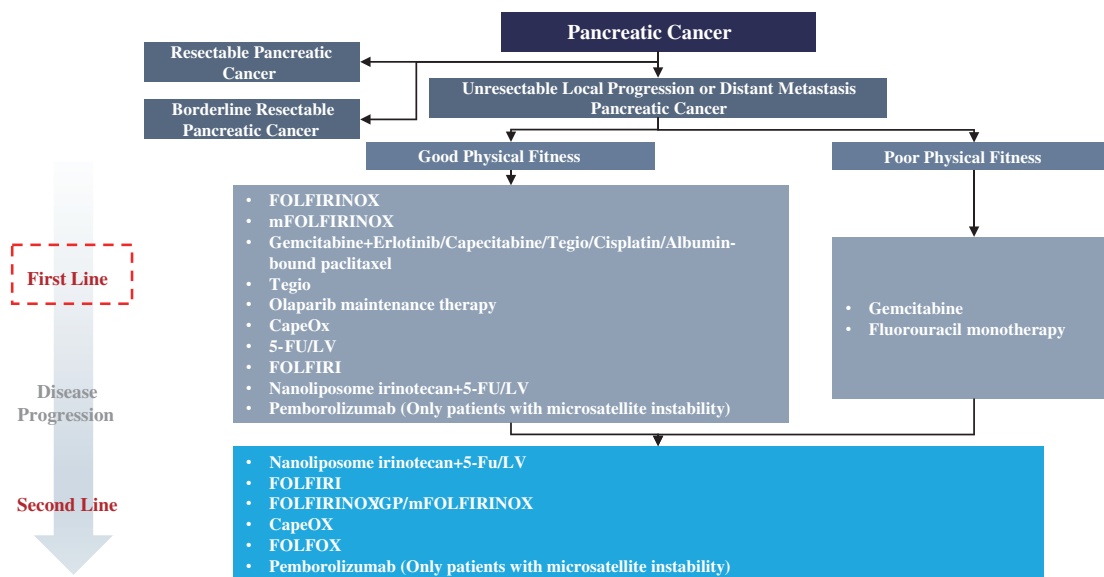
Source: NMPA, CDE, Frost & Sullivan Analysis

(1) “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

INDUSTRY OVERVIEW

Fusion protein refers to antibody fusion protein (Ig fusion protein), which is a bio-engineered protein that joins the biologically active protein domain with the fragment of an immunoglobulin. Antibody fusion proteins have the characteristics of antibodies and the activity of fusion functional proteins. According to the different Ig fragments bound, antibody fusion proteins can be divided into Fab fusion proteins, Fc fusion proteins, and single-chain antibody (scFv) fusion proteins. A BsAb is used to describe a large family of molecules designed to recognize two different epitopes or antigens. BsAbs come in many formats, ranging from relatively small proteins, which merely consist of two linked antigen-binding fragments, to large immunoglobulin G (IgG)-like molecules with additional domains attached. The different structures between BsAbs and fusion proteins are reflected in their molecular stability and clinical efficacy.

Treatment Paradigm for Pancreatic Cancer in China



First Line Intended position and clinical focus of the Company's drug candidate

Source: NHC, Diagnosis and treatment of pancreatic cancer (2018), Frost & Sullivan analysis

INDUSTRY OVERVIEW

The following table sets forth features and limitations of 1L treatments for late-stage pancreatic patients.

Method	Features	Limitations
Chemo (e.g. mFOLFIRINOX, Gemcitabine + albumin-bound paclitaxel)	1. Recommended as the 1st line regimens in the NCCN Guideline. 2. Toxicity could be tolerated, especially the Gemcitabine + albumin-bound paclitaxel regimen.	1. The current ORR (5-11%) is still not satisfied, new mechanism for better efficacy is needed. 2. Drug resistance happens usually after one year treatment. TKI therapy may be less effective for patients with advanced liver disease. The guidelines only recommend the use of TKIs in patients with less severe sclerosis.
Anti-PD-L1/PD-1 antibody (e.g. Pembrolizumab)	Broad-spectrum antitumor properties	High price, which imposes a huge financial burden on patients. Only useful in certain circumstance (if MSI-H, dMMR, or TMB-H [≥ 10 mut/Mb])

Intended position and clinical focus of the Company’s drug candidate

INDUSTRY OVERVIEW

Treatment Paradigm for HCC

HCC Treatment Paradigm		
Systemic Therapy	Systemic chemotherapy	FOLFOX 4
	Molecular targeted drug	1L: Donafeni, Lenvartini, sorafenib
	Immunotherapy	First line: Anti-PD(L)1 antibodies (Atezolizumab+bevacizumab, Sintilimab+bevacizumabanalogues) Second line: Regofinib*, Apatinib*, Karelizumab*, Tirelizumab*

Intended position and clinical focus of the Company’s drug candidate

Source: NHC, Frost & Sullivan analysis

* Drugs that are not yet approved in China.

INDUSTRY OVERVIEW

The following table sets forth features and limitations of treatments for late-stage HCC patients.

Method	Features	Limitations
Anti-PD-L1/PD-1 antibody (e.g. Atezolizumab)+anti-VEGF antibody (e.g. Bevacizumab)	1. Recommended as the 1st line regimens in the Guidelines, and better performance of Sorafenib. 2. Bevacizumab inhibits tumor angiogenesis, while further enhancing the ability of atezolizumab to restore the body's anti-cancer immunity by suppressing VEGF-related immunosuppression, promoting T-cell tumor infiltration, and initiating T-cell responses to tumor antigens.	1. The current ORR (20-30%) is still not satisfied, new mechanism for better efficacy is needed. 2. The choice of backbone therapy is unclear when progression happens after this combination therapy
TKI (e.g. Sorafenib, Lenvatinib)	1. Recommended as the 1st line regimens in the Guidelines. 2. Sorafenib and lenvatinib are well tolerated.	1. The current ORR (5-11%) is still not satisfied, a new mechanism for better efficacy is needed. 2. Drug resistance happens usually after one-year of treatment. TKI therapy may be less effective for patients with advanced liver disease. The guidelines only recommend the use of TKIs in patients with less severe sclerosis.
Anti-PD-L1 antibody + Anti-CTLA-4 antibody	1. Recommended as the 1st line regimens in the NCCN Guideline. 2. CTLA-4 and PD-L1 inhibitor combination has shown additive antitumor activity associated with complementary immunostimulatory effects.	1. This regimen is approved only in USA. More clinical evidence may be required for an approval in other countries. 2. The side effects are severe and alerted by NCCN guidelines. 3. The current ORR (20%) is still not satisfied. new mechanism for better efficacy is needed.
Anti-PD-1 or PD-L1 antibody alone	Recommended as the 1st and 2nd line regimens in the Guidelines or in certain circumstances.	1. The current ORR (10-15%) is still not satisfied, new mechanism for better efficacy is required. 2. The application scenario is very limited. 3. The efficacy is noninferior to sorafenib as the 1st line regimens.

Intended position and clinical focus of the Company's drug candidate

INDUSTRY OVERVIEW

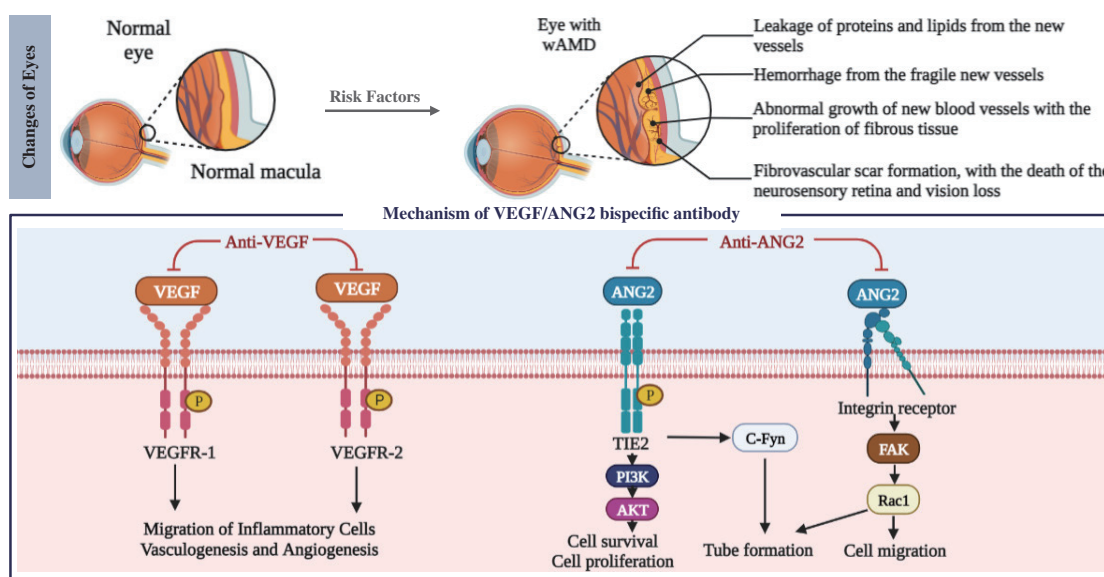
The development of combination therapy of PD-1 and TGF- β in cancer treatment is a validated therapeutic strategy. For instance, in 2021, Novartis AG completed a Phase I/Ib clinical trial of NIS793 (a TGF- β targeted mAb) in combination with PDR001 (a PD-1 mAb) in patients with advanced malignancies. Based on the results reported, NIS793 as single agent and in combination with PDR001 was effective in subjects with advanced malignancies. Such study identified new opportunities for the combination of PD-1 and TGF- β in cancer treatment. Encouraging efficacy results were also observed in the Phase I study of bintrafusp alfa, a bifunctional fusion protein targeting TGF- β and PD-L1, in patients with pretreated biliary tract cancer, indicating the potential of PD-1/PD-L1 $\times$ TGF- β targeted monotherapies in treating solid tumors.

PD-L1 $\times$ TGF- β targeted combination therapies are under clinical development. The Phase Ib/II clinical trial of SHR-1701, a PD-L1 $\times$ TGF- β targeted fusion protein, in combination with gemcitabine and nab-paclitaxel has demonstrated the preliminary efficacy in treating patients with untreated locally advanced or metastatic pancreatic cancer. The CDE has also approved the Phase II/III clinical trial in China to evaluate the safety and clinical efficacy of SHR-1701 in combination with BP102 (biosimilar to bevacizumab) and XELOX in first-line treatment of patients with metastatic colorectal cancer, indicating the therapeutic potentials of PD-L1 $\times$ TGF- β BsAbs for metastatic colorectal cancer treatment.

VEGF $\times$ ANG2 TARGETED BISPECIFIC ANTIBODY MARKET

Mechanisms of VEGF $\times$ ANG2 Targeted BsAb

Vascular endothelial growth factor (VEGF) and angiopoietin-2 (ANG2) are important proteins functioning in vasculogenesis, angiogenesis and cell migration. Abnormal upregulation of those molecules causes inflammation and destabilizes the endothelial cell layer, which then leads to hypervascular permeability. The VEGF $\times$ ANG2 BsAb simultaneously binds to both VEGF and ANG2 and prevents the endothelial barrier from breakdown, which diminishes the symptoms of wet age-related macular degeneration (wAMD) and diabetic macular edema (DME). The diagram below illustrates the mechanism of action of the VEGF $\times$ ANG2 BsAb:



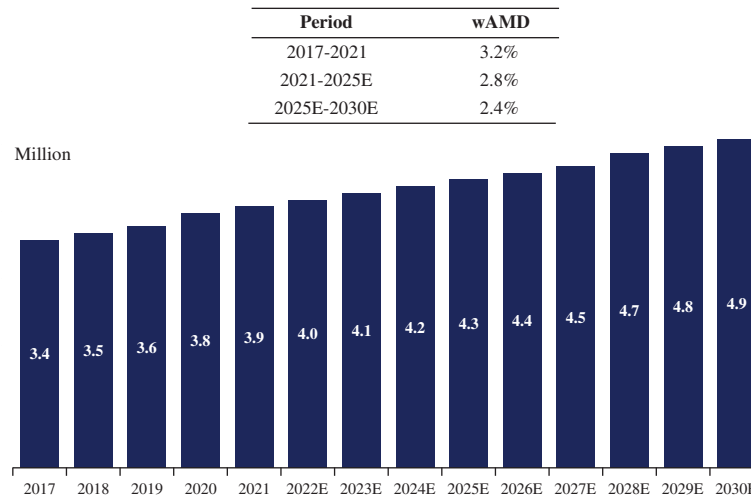
Source: *Biomedicines*. 2022 Aug 17;10(8):1996., *Cells*, 2019, 8(5): 471., *Expert Opinion on Investigational Drugs*, 2021, 30(3): 193-200., *J Ophthalmol*. 2012;2012:786870. Frost & Sullivan Analysis

INDUSTRY OVERVIEW

China’s Market of wAMD and DME Treatment

According to Frost & Sullivan, the simultaneous neutralization of VEGF and ANG2 has been envisioned as a novel candidate approach to wAMD and DME with better efficacy as a consequence of extended durability. The pool of wAMD and DME patients in China will steadily increase due to the growth of the aging population. From 2017 to 2021, the number of wAMD patients in China increased from 3.4 million to 3.9 million, representing a CAGR of 3.2%. It is estimated that wAMD patients in China will reach 4.3 million by 2025 and 4.9 million by 2030, representing a CAGR of 2.8% and 2.4%, respectively. The addressable wAMD patients of Y400, covers patients who are willing to receive treatment for wAMD. According to the White Paper of China Eye Health and Frost & Sullivan, the treatment rate for wAMD is approximate 70.0%, resulting in an estimated addressable wAMD patients of Y400 of 3.4 million in 2030 in China.

China’s Prevalence of wAMD, 2017-2030E



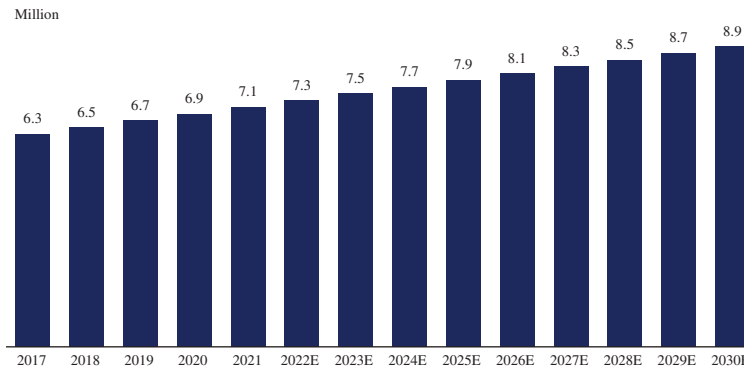
Source: NCCR, Frost & Sullivan analysis

From 2017 to 2021, the number of DME patients increased from 6.3 million to 7.1 million, representing a CAGR of 2.8%. It is estimated that DME patients in China will reach 7.9 million by 2025 and 8.9 million by 2030, representing a CAGR of 2.7% and 2.3%, respectively. The addressable DME patient of Y400, covers patients who are willing to receive treatment for DME. According to published research paper and Frost & Sullivan, the annual treatment rate for DME is approximate 30.0%, resulting in an addressable DME patients of Y400 of 2.7 million in 2030 in China.

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China’s Prevalence of DME, 2017-2030E

Period	CAGR
2021-2021	2.8%
2021-2025E	2.7%
2025E-2030E	2.3%

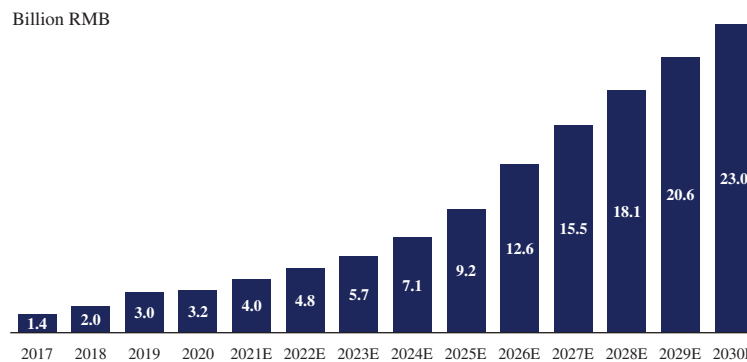


Source: NCCR, Frost & Sullivan Analysis

According to Frost & Sullivan, the market size of anti-VEGF mAb for retinal disease in China is experiencing a rapid growth. The market size of anti-VEGF mAb for retinal disease in China has grown from RMB1.4 billion in 2017 to RMB3.2 billion in 2020, with a CAGR of 32.7%. The market will keep growing to RMB9.2 billion in 2025 and RMB23.0 billion in 2030, with a CAGR of 23.8% and 20.1% respectively.

China Market Size of Anti-VEGF mAb for Retinal Diseases, 2017-2030E

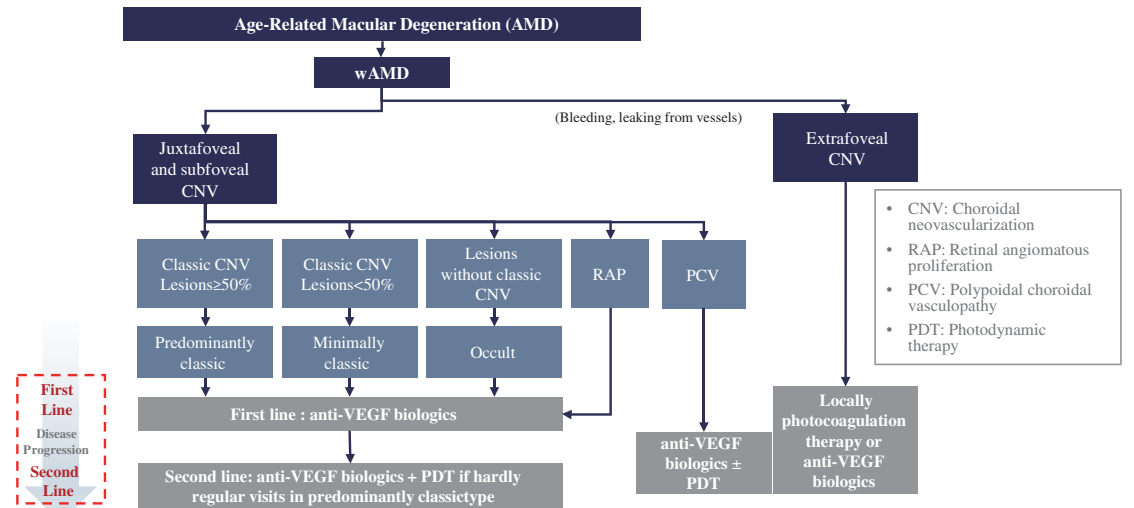
Period	CAGR
2017-2020	32.7%
2020-2025E	23.8%
2025E-2030E	20.1%



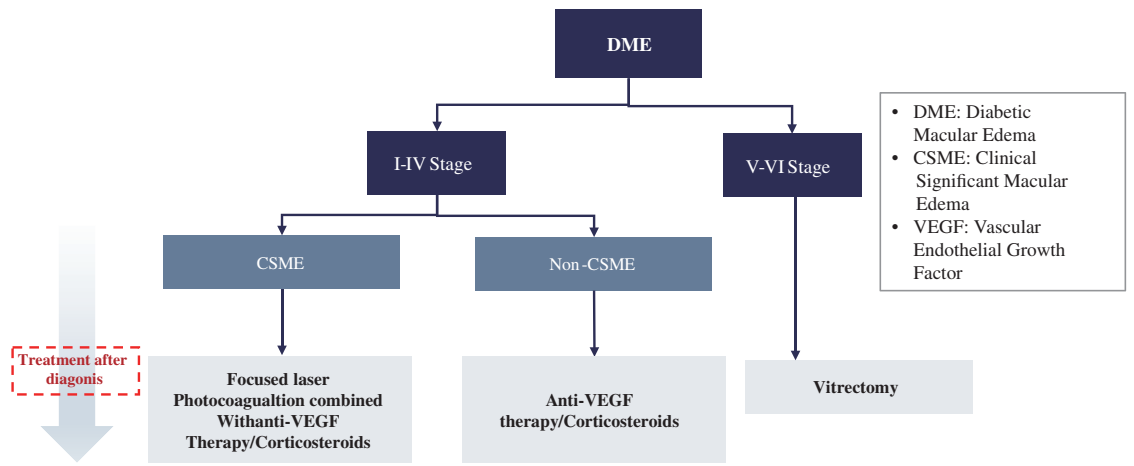
Source: Annual Reports of Listed Medical Companies, NCCR, MOHRSS, Frost & Sullivan Analysis

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Treatment Paradigm for wAMD and DME in China and Globally



Source: CMA, Literature Review, Frost & Sullivan Analysis



Source: IDF, Frost & Sullivan Analysis

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The following table sets forth features and limitations of treatments for wAMD and DME patients.

Major Treatments	Features	Limitations
photo-dynamic therapy, PDT	Making photosensitive drugs work under the action of laser. Destroying neovascularization and slowing down the rate of vision loss. The photosensitizer is first injected intravenously and then activated with a laser to close the neovascularisation using a photochemical effect. Combination with anti-VEGF antibodies can reduce the number of treatment.	Photosensitivity phenomenon causes the pain, swelling, bleeding or inflammation at the injection site. Used alone only for subtypes of typical subcentral sulcus choroidal neovascularization, with a small scope of application; Expensive photosensitizer (over RMB 10,000 per vial in China)
Laser Photocoagulation	Help patients with fundus disease avoid retinal detachment. Reduce the formation of new blood vessels in the eye; It is being phased out	Burning of vascular structures by a high-energy laser beam is only indicated for lesions far from the central macular recess. This may damage the nerve fibre layer and leave a dark spot in the visual field.
Hormone therapy	Vitreous cavity injection for the treatment of DME is the first treatment choice for DME in a few specific cases	Require repeated intraocular injections and poor patient compliance. The treatment cause intraocular hypertension and cataracts caused by the treatment
Anti-VEGF drugs	Significant improvement in neovascularization and endothelial cell proliferation. Reduced vascular permeability. The first treatment choice for wAMD and DME, for which the treatment has a more definitive effects and can significantly improve vision	VEGF mAbs require repeated intraocular injections which causes infections and poor patient compliance. Some patients develop drug resistance after long-term anti-VEGF mAbs. Thus more efficient regimens targeting VEGF are needed.

Intended position and clinical focus of the Company’s drug candidate

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Competitive Landscape of wAMD and DME VEGF Targeted and ANG2 Targeted Drugs

As of the Latest Practicable Date, there were seven VEGF targeted antibody drugs or fusion proteins approved for the treatment of wAMD and DME globally (excluding China), at price ranging from US\$783 per box to US\$8,433 per box and three approved in China. VEGF targeted antibody drugs or fusion proteins can also be used in combination with other drugs, such as Dexamethasone, for the treatment of solid tumors.

The following table sets forth the details of the three marketed VEGF targeted antibody drugs or fusion proteins for the treatment of wAMD and DME in China as of the Latest Practicable Date:

China Marketed Drugs								
Product	Drug Name	Developer	Target	Drug Type	Indication	Approval Date	Price (RMB) in 2021	Combination Therapy
Lucentis	Ranibizumab	Novartis Pharma Schweiz AG	VEGF	mAb	wAMD, DME	September 16, 2021	10mg/ml 0.2ml: 3,950	Combination with photodynamic therapy for wAMD
Lumitin	Conbercept Ophthalmic Injection	Chengdu Kanghong Biotechnology Co., Ltd.	VEGF	Fusion Protein	wAMD, DME, choroidal neovascularization and retinal vein occlusion secondary to macular edema	May 29, 2018	10mg/ml 0.2ml: 4,160	N/A
Eylea	Aflibercept Intravitreal Injection	Vetter Pharma-Fertigung GmbH & Co. KG	VEGF	Fusion Protein	wAMD, DME	February 2, 2018	40mg/ml 4mg: 4,100	Combination with subthreshold laser for diabetic macular edema treatment

Source: NMPA, Annual Reports of Listed Medical Companies, NRDL, Frost & Sullivan

As of the Latest Practicable Date, there were 56 and 15 VEGF targeted antibody or fusion protein drug candidates for the treatment of wAMD and DME under clinical development globally (excluding China) and in China, respectively. According to the CDE website, among the 15 VEGF targeted antibody or fusion protein drug candidate pipelines for wAMD and DME under clinical development in China, eight were in Phase III clinical trials, two were in Phase II clinical trials and five were in Phase I clinical trials. In addition to VEGF targeted antibody or fusion proteins, there are three drug candidates in China utilizing different methods in treating wAMD and DME under clinical development, including chemical drugs and gene treatments.

ANG2 is an important target for wAMD and DME treatment, for its possibly complementary or synergistic functions with other targets in tumor progressions. As of the Latest Practicable Date, only one ANG2 targeted antibody drug was approved for the treatment of wAMD and DME globally. As of the same date, there were seven and two ANG2 targeted antibody drug candidates or fusion proteins for the treatment of wAMD and DME under clinical development globally (excluding China) and in China, respectively. The following table sets forth the details of the one marketed ANG2 targeted drug globally as of the Latest Practicable Date:

Global Marketed Drugs							
Product	Drug Name	Developer	Target	Drug Type	Indication	Approval Date	Price (USD)
VABYSMO	Faricimab	GENENTECH, INC.	VEGF, ANG2	BsAb	wAMD and DME	January 28, 2022	6mg/0.05ml 0.05ml: 2,315

Source: FDA, Annual Reports of Listed Medical Companies, Frost & Sullivan

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The successful commercialization of VABYSMO evidenced the therapeutic potentials of VEGF × ANG2 BsAbs, including Y400, for treating wAMD and DME.

Among all the VEGF targeted drugs, VEGF × ANG2 drug candidates represent an emerging trend. As of the Latest Practicable Date, there were three VEGF × ANG2 drug candidates for treating neovascular eye diseases under clinical development in China:

China Pipeline							
Product	Drug Name	Developer	Target	Drug Type	Indication	Highest Clinical Phase	First Posted Date ⁽¹⁾
Faricimab Injection	Faricimab	F. Hoffmann-La Roche Ltd	ANG2, VEGF	BsAb	DME, macular edema secondary to branch RVO, wAMD, CRVO or hemi retinal vein occlusion secondary to macular edema, polypoidal choroidal vasculopathy	III	2021/7/6
IBI324	IBI324	Innovent Biologics (Suzhou) Co., Ltd.	VEGF, ANG2	BsAb	DME	I	2022/6/17
ASKG-712	ASKG-712	Suzhou Aosaikang Biopharmaceutical Co., Ltd.	ANG2, VEGF	Fusion Protein	wAMD	I	2022/7/29

Source: NMPA, CDE, Frost & Sullivan Analysis

Abbreviations: RVO refers to retinal vein occlusion; CRVO refers to central retinal vein occlusion.

(1) “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

For a comparison of BsAbs and fusion proteins, please refer to the above section headed “Competitive Landscape of PD-1/PD-L1 × TGF-β Targeted Drugs”.

As Y400 received the IND approval in April 2023, it’s still at very early clinical development stage when compared to other VEGF targeted therapies and ANG2 targeted therapies, and face fierce competition for the treatment of wAMD and DME.

Future Trends and Needs of wAMD and DME Treatment

The future trends of wAMD and DME treatment mainly include: (a) an enlarged market size as wAMD’s incidence increases with aging, and with the growth of the aging population in China, it is expected that wAMD patients in China will also grow and demand for effective treatment will increase; (b) the improved administration of drugs given the development of gene therapy in wAMD treatment, which allows patients to avoid eye injections and get more comfortable with alternative methods of administration; (c) the innovation of more durable treatments, since currently the intravitreal injection of anti-VEGF mAb drugs is inefficient in inhibiting angiogenesis, which calls for more durable drugs that could block both VEGF and other angiogenic factors; (d) the improved awareness of pre-clinical diagnosis of DME, which allows early detection and treatment; (e) the development of combination therapies that can reduce the incidence of certain complications of DME; and (f) the introduction of innovative therapies that have higher efficacy, while reducing patient discomfort, thereby improving patient compliance.

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Despite the continuous development of therapies to address the demands of wAMD and DME patients, there remain medical demands, including the following: (a) intraocular injections of anti-VEGF drugs require frequent injections to have a good therapeutic effect, but frequent dosing can impose a financial burden to the patients; (b) photodynamic therapy (PDT) may result in inadequate choroidal perfusion, which is a significant inflammatory response at the treated site and increased VEGF expression, with a risk of compromising long-term visual prognosis and a high recurrence rate; (c) in addition to overcoming fear with each injection, patients also face the risk of infection due to frequent injections, and anti-VEGF therapy has limited effect on reducing the inflammation that leads to wAMD; (d) the inconvenience of drug administration, as most drugs are given by eye injection, which lack durability and intensifies inconvenience. Additionally, wAMD patients need to have eye injections every one or two months, which leads to low patient compliance; (e) the inefficiency of the intravitreal injection of VEGF drugs, since single-target VEGF inhibitors promote the upregulation of other angiogenic factors, which impairs the efficacy of treatment; and (f) difficulties of diagnosis, as few symptoms of DME could be diagnosed in the early stages, and since DME is a common complication of diabetes, its treatments are often associated with diabetic medicines, which have known adverse effects such as headaches and drug resistance.

VEGF × TGF-β TARGETED BISPECIFIC ANTIBODY MARKET

VEGF is a growth factor overexpressed in most solid tumors and a key driver of angiogenesis, the process that leads to the formation of new blood vessels within and around tumors. In addition to stimulating tumor angiogenesis, VEGF plays a negative role in tumor immunity via various mechanisms within the TME. TGF-β also negatively regulates multiple immune cells, facilitates the generation of CAF and stimulates the EMT process of tumor cells that restricts T cell infiltration.

As of the Latest Practicable Date, no VEGF × TGF-β targeted drugs were marketed either globally or in China. As of the same date, one VEGF × TGF-β targeted BsAb and one PD-L1 × VEGF × TGF-β fusion protein were under clinical trials globally.

Global Pipeline							
Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date ⁽¹⁾
PM8003	Biotheus Inc.	PD-L1, VEGF, TGF-β	Fusion protein	Advanced Solid Tumor	China	I	2021/7/30
ZGGS18	Suzhou Zelgen Biopharmaceuticals Co., Ltd.	VEGF, TGF-β	BsAb	Advanced Solid Tumor	Global China	FDA IND Approval I/II	\ 2022/10/20

Source: NMPA, CDE, FDA, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

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For a comparison of BsAbs and fusion protein, please refer to the above section headed “Competitive Landscape of PD-1/PD-L1 × TGF-β Targeted Drugs”.

Both the TGF-β and VEGF pathways are the representative pathways of the innate anti-PD-1 resistance signatures, related to immunosuppressive processes. Therapeutic agents targeting TGF-β and VEGF, may synergize with existing immunotherapies to overcome immune checkpoint blockade resistance, indicating great therapeutic potentials of TGF-β targeted drugs for solid tumor treatment. The combination of PD-1 and TGF-β in cancer treatment have been clinically validated. For instance, Avastin (bevacizumab), a VEGF targeted mAb, is approved to treat several solid tumors, including metastatic colorectal cancer, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, relapsed glioblastoma, hepatocellular carcinoma, metastatic HER2-negative breast cancer, epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer and cervical cancer.

CHINA’S COVID-19 VACCINE MARKET

Overview

The COVID-19 pandemic is an ongoing public health crisis caused by infections and spread of the severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2. Recent mutated variants of the virus have emerged, some are more aggressive and infectious. According to the World Health Organization, until November 28, 2022, there were 637 million confirmed COVID-19 cases and over 6.6 million related deaths worldwide. After a brief rebound in 2021, the new variants of the COVID-19 virus, among other factors, have caused a significant slowdown of the global economy in 2022. In response to the COVID-19 pandemic, the international community has continued to concentrate research and development efforts on combating the pandemic, and ensure global access to diagnostic equipment, therapies, vaccines and other resources.

Types of COVID-19 Vaccines

COVID-19 vaccines are developed using a number of classic and innovative technologies, of which four technology routes have generated approved products: inactivated vaccine, recombinant subunit protein vaccine, viral vector vaccine and nucleic acid vaccine. These technology routes have different benefits and limitations in terms of safety, efficacy, supply and storage conditions, and therefore are suitable to different population segments with different vaccination history and needs, immunity conditions and technology preferences. When compared to other technology routes, the recombinant subunit protein vaccine is safe and effective, represents an established technical pathway, and could achieve scalable manufacturing.

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Main Technical Classification of COVID-19 Vaccines

	Mechanism	Advantage	Limitation
Inactivated Vaccine	Use killed pathogen to induce the production of antibodies	Established technical pathway; Quick and scalable manufacturing; Effective;	Large dose; May cause antibody-dependent enhancement (ADE);
Recombinant Subunit Protein Vaccine	Use the spike (S) protein of SARS-CoV-2 as the antigen to induce the production of antibodies	Safe and effective; Established technical pathway; Scalable manufacturing;	Antigenicity subject to the expression system
Viral Vector Vaccine	Use viral vector that cause no harm to human body to carry the gene of the spike (S) protein into the body, and produce the spike (S) protein to trigger production of antibodies	Safe and effective; Few side effects; Easy administration and less doses taken;	Long R&D process; May have pre-existing immunity (has infected with the vector virus before so that there are neutralizing antibodies against the vector virus in the body)
Nucleic Acid Vaccine	Direct injection of the gene of the spike (S) protein, use human cell to produce antigen and then trigger production of antibodies	No need to express protein or virus during manufacturing; Safe	Scalable manufacturing process need optimization; mRNA is not stable; Difficult for the vaccine to enter cells

Source: WHO, CDC, Chavda, V. P., Hossain, M. K., Beladiya, J., & Apostolopoulos, V. (2021). Nucleic acid vaccines for COVID-19: a paradigm shift in the vaccine development arena. *Biologics*, 1(3), 337-356.; Heidary, M., Kaviar, V. H., Shirani, M., Ghanavati, R., Motahar, M., Sholeh, M., Ghahramanpour, H., & Khoshnood, S. (2022). A Comprehensive Review of the Protein Subunit Vaccines Against COVID-19. *Frontiers in microbiology*, 13, 927306. <https://doi.org/10.3389/fmicb.2022.927306>; Vanaparthi, R., Mohan, G., Vasireddy, D., & Atluri, P. (2021). Review of COVID-19 viral vector-based vaccines and COVID-19 variants. *Le infezioni in medicina*, 29(3), 328 -338. <https://doi.org/10.53854/liim-2903-3>; Khoshnood, S., Arshadi, M., Akrami, S., Koupaei, M., Ghahramanpour, H., Shariati, A., ... & Heidary, M. (2022). An overview on inactivated and liveattenuated SARS-CoV-2 vaccines. *Journal of Clinical Laboratory Analysis*, 36(5), e24418.

Demand for COVID-19 Vaccines

Different variants of the SARS-CoV-2 virus have emerged and are circulating globally including in China. New information about the characteristics of these variants is rapidly emerging, and there is a growing public awareness of the necessity to receive vaccination against emerging variant strains. As a result, additional boosting might be required because of waning immunity to the primary vaccination. Some recent studies have shown that the antibody concentration declined in the third month after administration of two doses of inactivated vaccines, and the protection rate of currently approved mRNA vaccines declined to approximately 40% in six months. These indicate a significantly larger and longer-term market demand for booster shots and re-vaccination of COVID-19 vaccines.

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There is a global shortage of COVID-19 vaccines which is caused by the limited supply capacity as compared to the vast global population to be vaccinated and uneven access to COVID-19 vaccines among nations. As of December 31, 2021, the vaccination rate in China and globally were 51.2% and 57.2%, respectively. From March 23, 2021 to December 31, 2021, the total COVID-19 vaccine doses administered in China and globally were 2.8 billion and 39.7 billion, respectively. While COVID-19 continues to spread and as new variants emerge in countries without access to adequate supply of COVID-19 vaccines, there is a huge market gap that needs to be met urgently in order to achieve herd immunity against COVID-19 globally.

Competitive Landscape of COVID-19 Vaccines in China and Globally

As of the Latest Practicable Date, 15 COVID-19 vaccines had received marketing approvals in the PRC, consisting of five inactivated vaccines, three recombinant adenovirus viral vector-based, six recombinant subunit protein vaccines and one mRNA vaccine. As of the same date, 32 clinical-stage COVID-19 pipeline candidates in the PRC were being developed, including nine using the recombinant subunit protein route, according to the CDE and WHO websites.

Additionally, as of the Latest Practicable Date, 58 COVID-19 vaccines had received marketing approvals globally, consisting of 13 inactivated vaccines, 12 recombinant adenovirus viral vector-based, 22 recombinant subunit protein vaccines, 11 nucleic acid vaccines, and 242 clinical-stage COVID-19 pipeline candidates were being developed globally, of which 79 were using the recombinant subunit protein route, according to the CDE and WHO websites.

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Competitive Landscape of Marketed COVID-19 Vaccines in China

The chart below illustrates the marketed COVID-19 vaccines in China as of the Latest Practicable Date.

Product Name	Company	Technology	Route of Administration	Dosages Per Year	Approval Time	Effectiveness of Protection against Different Variants
科兴瑞 克尔来福 (CoronaVac)	Institute of Medical Biology, Chinese Academy of Medical Sciences Beijing Xing Zhongwei Biotechnology Co., Ltd.	Inactivated Vaccine Inactivated Vaccine	Intramuscular injection Intramuscular injection	2 2	6/9/2021 2/5/2021	Good safety and immunogenicity had the ability to cross-neutralize against the new crown strain from Turkey The interim analysis in Turkey was able to achieve a protection rate of 91.25%, and the results of the phase III clinical study in Indonesia have been published, with a protection rate of 65.3%. The protection rate for medical visits reached 78%. The overall protection rate for health care workers in high-risk groups is also 50.3%.
可维克 (KOVAC)	Shenzhen Kangai Biological Products Co., Ltd.	Inactivated Vaccine	Intramuscular injection	2	5/14/2021	The geometric mean titer (GMT) of live virus neutralizing antibody in the 0-28 day immunization program vaccine group in the phase I and II clinical trials of this vaccine was 131.7, which was 2.65 times higher than the GMT of 49.7 in serum neutralizing antibody in recovered patients. According to the data from the phase I/II clinical trial of Kangai Bio New Crown vaccine, this vaccine did not cause any serious adverse reactions of grade 3 or above, and the overall incidence of adverse reactions was not significantly different compared with the placebo group.
众康可维 (WHBP-CovV)	Wuhan Biological Products Research Institute Co., Ltd.	Inactivated Vaccine	Intramuscular injection	2	2/5/2021	JAMA journal published online the data of the phase III clinical interim detailed analysis of two inactivated new crown vaccines from Beijing Institute and Wuhan Institute, a subsidiary of Sinopharm China Biological Group. The results showed that the vaccine efficacy was 78.1% for Zougangwei compared to using only aluminum adjuvant alone.
众康可维 (BBIBP-CovV)	Beijing Institute of Biological products CO., LTD	Inactivated Vaccine	Intramuscular injection	2	12/29/2020	JAMA journal published online the data of the phase III clinical interim detailed analysis of two inactivated new crown vaccines from Beijing Institute and Wuhan Institute, a subsidiary of Sinopharm China Biological Group. The results showed that the vaccine efficacy was 72.8% for Zougangwei compared to using only aluminum adjuvant alone.
智克威得	Abuh Zhiwei Longcom Biopharmaceutical Co., Ltd	Recombinant Subunit Protein Vaccine (CHO Cell)	Intramuscular injection	3	3/1/2022	Published in the New England Journal of Medicine, the world's top academic journal, clinical results showed that the vaccine was 81.4% effective in preventing any severity of NCCPn in subjects who completed the full course of vaccination, and remained 75.7% effective in preventing any severity of NCCPn in a long-term effectiveness analysis 6 months after the full course of vaccination.
克威莎 (世柱式)	Cansino Biologics Inc.	Viral Vector Vaccine	Intramuscular injection	1	2/25/2021	Journal of Emerging Microorganisms and Infections: Preclinical results show that the novel coronavirus mRNA vaccine from Conception Biologics has strong immune protection against different new coronavirus variants. Two doses of mRNA-Beta induced broad protection against both the original strain and the Beta variant. At the same time, the use of mRNA-Omicron as a booster, either homologous booster for mRNA-Beta or heterologous sequential booster for Covivax's new recombinant coronavirus vaccine Ksiva, significantly increased the level of neutralizing antibodies against the four strains, especially against the Omicron variant, providing durable and efficient protection
克威莎 (世柱式)	Cansino Biologics Inc.	Viral Vector Vaccine	Inhalation	1	3/1/2021	Immunogenicity results showed that after 28 days of sequential booster immunization on with inhalation between neutralizing antibody levels against the original strain were 18.4-26.4 times higher in the two dose groups than in the inactivated homologous booster group (GMT 1937.3 in the low dose group, GMT 1350.8 in the high dose group, and GMT 73.5 in the inactivated homologous booster group). Also, sequential booster inhalation Novecrown vaccine had high levels of cross-protection against delta mutant strains, with 18.1-34-fold higher levels of neutralizing antibodies than inactivated vaccine. Inhalation biohazardor also efficiently induced mucosal immunity. The results of RBD-specific IgA conjugated antibody levels in serum of subjects within 28 days after booster immunization showed that the booster immunization had a higher level of neutralizing antibody than those of inactivated vaccine homologous booster, with GMT 114.3 in the low-dose group, GMT 116.2 in the high-dose group and GMT 11.2 in the inactivated homologous booster group
丽珠V-01	Lizhi Pharmaceutical Group Co., Jiokeai Pharmaceutical Group Industry Co., Ltd.	Recombinant Subunit Protein Vaccine (CHO Cell)	Intramuscular injection	1	9/14/2022	The absolute protection rate is 61.35% with the sequential booster of Likang V-01 on top of the two inactivated vaccines, including 61.19% for the high-risk group (people over 60 years old or with underlying diseases) and 71.85% for people with underlying diseases. In terms of safety, the safety of Likang V-01 is significantly better than that of mRNA vaccine and adenovirus vaccine. Most of the adverse events (AE) were mild, with recruitment AEs (injection site pain, headache, fatigue, fever, non-vaccination site muscle pain) data significantly lower than those of the mRNA vaccine, which can provide safer protection.
SCTV01C	Sinocelltech Group Limited	Recombinant Subunit Protein Vaccine	Intramuscular injection	1	12/4/2022 (emergency use)	The results of three completed clinical studies showed that SCTV01C exhibited outstanding immunopersistence after immunization.
威克欣	WestVac Biopharma Co., Ltd, West China Hospital of Sichuan University	Recombinant Subunit Protein Vaccine (S19 Cell)	Intramuscular injection	3	12/2/2022 (emergency use)	Both the BA.1 and BA.5 variants of the currently prevalent Omicron strains induced uniformly high neutralizing antibody titers against the true virus. In addition, booster immunization with SCTV01C maintained high neutralizing antibody titers in the range of 170-678 at 12 months, demonstrating the outstanding immune durability of SCTV01C.
SCB-2019	Sichuan Clover Biopharmaceuticals Co., Ltd., GlaxoSmithKline Pharmaceuticals	Recombinant Subunit Protein Vaccine (CHO Cell)	Intramuscular injection	2	12/25/2022 (emergency use)	New phase III data demonstrating broad-spectrum neutralization – including against the globally dominant sub-type of Omicron BA.5 variant – underscore the potential role of SCB-2019 (CpG 1018/aluminum adjuvant) as a universal booster in China and other countries, regardless of prior vaccination route or history of infection, and for different age groups.
DNBS-2019 ICAN-BBD-0PT1	Beijing Wanlai Biological Pharmaceutical Co.	Viral Vector Vaccine	Nasal spray drug delivery	2	12/2/2022 (emergency use)	Induction of strong innate and acquired local immune responses in the respiratory tract, rapid (24-hour onset of action), durable and broad protection against SARS-CoV-2 attack in hamsters, even when administered 24 hours after SARS-CoV-2 infection. Nine months after vaccination with two doses of DNBS-RED, the protection provided by vaccination against the SARS-CoV-2 beta variant remained as good as that against the original virus strain.
SCTV01E	Sinocelltech Group Limited	Recombinant Subunit Protein Vaccine	Intramuscular injection	1	3/23/2023 (emergency use)	It is showed that during the epidemic of Omicron BA.5, B.7 and XBB variants in China, SCTV01E produced good protective efficacy against Omicron and its variants with good safety after one dose of enhanced immunization in people 2-18 years of age who had completed basic or enhanced immunization against COVID-19 vaccine. The Phase III clinical study also observed for the first time the protective efficacy of COVID-19 vaccine against asymptomatic infection, with the protective efficacy of 100% and 42.9% for asymptomatic patients 14 and 7 days after vaccination, respectively.
SY56006	CSNPC Pharmaceutical Group	mRNA	Intramuscular injection	1	3/23/2023 (emergency use)	After receiving one booster dose of SY56006, the geometric mean titer of neutralizing antibodies (GMT) against Omicron BA.5 was 236, which is 83 times higher than before the booster shot was given. For those who received either 2 or 3 doses of the inactivated vaccine, the sequential boosting immunization with one dose of SY56006 showed cross-neutralizing effects against strains such as Omicron BA.5, B.67, BQ.1.1, XBB.1.5, and CH.1.1.

Source: NMPA, CDE, FDA, WHO, Medicine Instructions, Clinical Trials, Frost & Sullivan

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Competitive Landscape of Recombinant Subunit Protein COVID-19 Vaccines in China

As of the Latest Practicable Date, there were nine recombinant subunit protein COVID-19 vaccines in China under clinical development, including Y2019. The chart below illustrates the marketed recombinant subunit protein COVID-19 vaccines under development in China as of the Latest Practicable Date:

China Marketed Products					
Product	Company	Medicine	Indication	Approval Time	
智克威得	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd	Recombinant Subunit Protein Vaccine(CHO Cell)	COVID-19	2022/3/1	
麗康V-01	Lizhu Pharmaceutical Group Co., JoincarePharmaceutical Group Industry Co., Ltd.	Recombinant Subunit Protein Vaccine (CHO Cell)	COVID-19	2022/9/14	
SCTV01C	Sinocelltech Group Limited	Recombinant Subunit Protein Vaccine	COVID-19	2022/12/4 (for emergency use)	
威克欣	WestVac Biopharma Co.,Ltd, West China Hospital of Sichuan University	Recombinant Subunit Protein Vaccine (Sf9 Cell)	COVID-19	2022/12/2 (for emergency use)	
SCB-2019	Sichuan Clover Biopharmaceuticals Co., Ltd., GlaxoSmithKline Pharmaceuticals	Recombinant Subunit Protein Vaccine (CHO Cell)	COVID-19	2022/12/5 (for emergency use)	

Source: Annual Reports of Listed Medical Companies, NMPA, CDE, Frost & Sullivan Analysis

(1) “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

The successful commercialization of the six recombinant subunit protein COVID-19 vaccines in China evidenced the great therapeutic potentials of recombinant subunit protein vaccines against SARS-CoV-2 and its VOCs.

REPORT COMMISSIONED BY FROST & SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the worldwide and China market. Frost & Sullivan is an independent global market research and consulting company which was 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. The contract sum to Frost & Sullivan is RMB900,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the results 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 have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the biologics market 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 believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, 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’s may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

REGULATORY OVERVIEW

PRC LAWS AND REGULATIONS

This section sets forth a summary of the relevant significant PRC laws and regulations that affect our business and the industry in which we operate.

Regulatory Authorities

In the PRC, the National Medical Products Administration, or the NMPA, which was previously known as China Food and Drug Administration, is the primary regulatory agency for pharmaceutical products and businesses and regulates almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e. post-marketing safety reporting obligations). The Center for Drug Evaluation, or the CDE, which is a subsidiary under the NMPA, conducts the technical evaluation on each drug and biologic application to assess the safety and efficacy of each candidate.

The National Health Commission, or the NHC (formerly known by names of the Ministry of Health and National Health and Family Planning Commission), is the primary healthcare regulatory agency in China. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites.

Also, the Ministry of Commerce, or the MOFCOM, and the State Administration for Market Regulation, or the SAMR, are the main regulatory authorities on our PRC subsidiaries with regard to the foreign investment activities and business supervision.

Laws and Regulations Related to Drugs

Introduction

In 2017, the drug regulatory system entered a new and significant period of reform. In October 2017, the General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in 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》) (the “**Innovation Opinion**”) to encourage, among others, the reform of clinical trial management and acceleration of the review and approval for drugs and medical devices marketing.

To implement the regulatory reform introduced by the Innovation Opinion, the National People’s Congress (the “NPC”) and NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law (《中華人民共和國藥品管理法》), or the Drug Administration Law. The Drug Administration Law was promulgated by the Standing Committee of the NPC (the “SCNPC”), on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The State Council issued the Regulations for Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實

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施條例》), which was promulgated on August 4, 2002 and latest amended on March 2, 2019, to further implement the Drug Administration Law. The NMPA also has its own set of regulations for the Drug Administration Law, and the primary one governing clinical trial applications, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation (《藥品註冊管理辦法》) (the “**Drug Registration Regulation**”), which was latest amended by the SAMR on January 22, 2020 and effective from July 1, 2020.

Non-Clinical Research and Animal Testing

The NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory (《藥物非臨床研究質量管理規範》) (the “**GLP**”) in 2003, which were revised on July 27, 2017, and has conducted the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory, or GLP Certification since 2003. On April 16, 2007, the NMPA issued the Circular on Measures for Certification of Good Laboratory Practice and for Non-clinical Laboratory (《藥物非臨床研究質量管理規範認證管理辦法》), or the NMPA Circular 214, last amended on January 19, 2023 and will come into effect on July 1, 2023, which sets forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical drug research.

The State Science and Technology Commission promulgated the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) in November, 1988, which were amended by the State Council in January 2011, July 2013 and March 2017. The State Science and Technology Commission and the State Bureau of Quality and Technical Supervision jointly promulgated the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) in December 1997. The State Science and Technology Commission and other regulatory authorities promulgated the Administrative Measures on the Certificate for Experimental Animals (for Trial implementation) (《實驗動物許可證管理辦法(試行)》) in December 2001. All of these laws and regulations require a Certificate for Use of Laboratory Animals for performing experimentation on animals.

Clinical Trials Approval

Before registering a new drug, a sponsor shall complete clinical trials according to the Drug Registration Regulation. To start the clinical trial, a sponsor needs to apply for clinical trial approval first, and the Administrative Regulations of Good Clinical Practice for Drug Trial (《藥物臨床試驗質量管理規範》) (the “**GCP**”), has been promulgated to further promote the research into good practice for clinical trials of drugs and enhance the quality thereof. The GCP was promulgated by NMPA on August 6, 2003 and latest amended by NMPA and NHC which came into effect on July 1, 2020. All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed according to the Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by NMPA and NHC on November 29, 2019.

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According to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration (《關於藥品註冊審評審批若干政策的公告》) promulgated by NMPA on November 11, 2015, an umbrella approval would be issued by NMPA for all phases of a new drug clinical trial, instead of approvals phase by phase. Provided by the Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial (《關於調整藥物臨床試驗審評審批程序的公告》) issued by NMPA on July 24, 2018, applicants could proceed with their clinical trials if they have not received any denial or query from the CDE within 60 business days after the application has been accepted and the relevant application fees have been paid. The newly revised Drug Administration Law further confirms that the CDE under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed approved. On May 22, 2017, NMPA issued the Announcement of the Opinions on Handling Issues Related to Verification of Drug Clinical Trial Data (《關於藥物臨床試驗數據核查有關問題處理意見的公告》), according to which, if the clinical trial data is incomplete, ill-formed and insufficient to prove the safety and efficacy of the drug, the registration application of the drug will be rejected.

Drug Clinical Trial Registration

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme of the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. More details are provided in the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) released by the NMPA on September 6, 2013, providing that for all clinical trials approved by the NMPA and conducted in China shall be published through the Drug Clinical Trial Registration and Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial’s unique registration number and shall complete certain follow-up information and first submission for publication before the first subject’s enrollment in the trial. If the foregoing first time of publication has not been submitted within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

Clinical Trial Process and Good Clinical Practices

Typically, pursuant to the Drug Registration Regulation, drug clinical trials in China shall go through four phases – phase I clinical trial, phase II clinical trial, phase III clinical trial and phase IV clinical trial. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research clinical. The NMPA requires that the different phases of clinical trials in China shall receive ethics committee approval respectively

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and comply with the relevant requirements of quality management standards for clinical trials of drugs in PRC. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

However, according to the Technical Guiding Principles for Clinical Trials of Anti-tumor Drugs (《抗腫瘤藥物臨床試驗技術指導原則》) issued by the NMPA on May 15, 2012, the clinical study staging of anti-tumor drugs is not a fixed developmental sequence. The rapid development of anti-tumor drug research theories and technologies is likely to have an impact on future anti-cancer drug development models. Therefore, applicants can actively explore more scientific and rational research methods and promptly seek advice from the drug registration department under the NMPA.

On November 19, 2021, the CDE introduced the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), or the Guiding Principle, for anti-tumor drugs, which states that the fundamental purpose of the drug market is to address the needs of patients, and emphasizes that drug research and development should be based on patient needs and clinical value. The Guiding Principle discourages repetitive research and development of “me-too drugs” (drugs with identical mechanisms of action) and excessive waste.

In terms of trial design for anti-tumor drugs, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. According to the GCP, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial, excluding the damages caused by the negligence of investigators or the clinical trial institution. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the GCP, and the protocols must be approved by the ethics committees. Pursuant to the newly amended Drug Administration Law and the Regulations on the Administration of Drug Clinical Trial Institution (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be subject to filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs are not required to perform filing procedures.

Human Genetic Resources Approval and Registration

The Ministry of Science and Technology promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《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》) in July 2015, according to which, if the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. On October 26,

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2017, the Ministry of Science and Technology issued the Announcement on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which simplified the approval for utilizing human genetic resources to obtain the marketing license of a drug in the PRC.

On May 28, 2019, the State Council of PRC issued the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) (the “**Human Genetic Resource Regulation**”), which became effective on July 1, 2019. According to the Human Genetic Resource Regulation, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilizing China’s human genetic resources in order to obtain market license at clinical institutions without involving the export of human genetic resources materials outside of China. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

Overseas Clinical Trial

On January 30, 2015, the CFDA promulgated the International Multi-Center Clinical Trial Guidelines (for Trial implementation) (《國際多中心藥物臨床試驗指南(試行)》) (the “**IMCT Guidelines**”), to provide guidance for the regulation of application, implementation and administration of international multicenter clinical trials in China. Where the applicant intends to make use of the data derived from international multi-center clinical trials for application for approval of drug application, it is necessary to conduct an overall evaluation of global clinical trial data, and then conduct further trend analysis on clinical trial data in Asia and our country. The similarity of the patients selected for clinical trial and general patients shall also be considered. The samples from trials in China shall be sufficient to evaluate and conclude the safeness and effectiveness of the drug for trial to patients in China and shall satisfy the statistics and legal requirements. Furthermore, the institutions involved in the international multi-center clinical trial shall be subject to on-site inspections by our drug administrative authorities.

On October 8, 2017, the General Office of Chinese Communist Party’s Central Committee and the General Office of the State Council jointly issued the Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (《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 stipulates that overseas clinical trial results are acceptable in China. Data derived from overseas clinical trials can be used in application for registration of drugs and medical devices if the data satisfy the registration requirement for drugs and medical devices in China. For initial application for marketing of pharmaceutical products and medical devices in China, the applicants are required to provide clinical trial data to indicate whether there will be difference of trial results among different ethnic groups.

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According to the Notice on Technical Guiding Principles for the Acceptance of the Overseas Clinical Trial Data of Drugs (《關於發佈接受藥品境外臨床試驗數據的技術指導原則的通告》) issued by NMPA on July 6, 2018, if overseas clinical trial data is used in application for drug registration, all (and not some) overseas clinical trial data shall be submitted. If a clinical trial is initially conducted in overseas and subsequent clinical trial will be conducted in China, the applicant of drug registration application is required to evaluate the data from initial clinical trial and to compile a full report. The applicant shall negotiate with the Drug Evaluation Center for acceptance of the initial clinical trial data for subsequent clinical trials.

New Drug Application and Registration

According to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization, and submit the relevant research materials in accordance with the submission requirements. The CDE shall organize pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. Where the application is cleared by the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued. Under the Drug Registration Regulation, drugs are classified into Chinese medicine, chemical medicine, biological products and others. Biological products are further divided in 3 categories in the Registration Classification and Application Documents Requirements of Biological Products (《生物製品註冊分類及申報資料要求》) (the “**Registration Category**”), which was promulgated by the NMPA on June 29, 2020 and replaced the previous version issued in 2007. Pursuant to the Registration Category, Category I therapeutic biological products or vaccines refer to those have not been marketed in the PRC or abroad. Category II therapeutic biological products or vaccines refer to improved ones which, compared with the existing products marked in the PRC or abroad, could improve the safety, effectiveness and quality controllability, and have obvious advantages. Category III therapeutic biological products or vaccines refer to those have been marketed in the PRC or abroad.

Pursuant to the newly amended Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognized as a drug marketing authorization holder, responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The drug marketing authorization holder may engage in manufacturing or distribution on its own or to entrust a licensed third party. At the time of application for drug marketing authorization, the applicant and the manufacturing enterprise shall have held the corresponding Pharmaceutical Manufacturing Permit.

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Accelerated Approval for Clinical Trial and Registration

The CFDA released 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》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, including but not limited to a one-time umbrella approval procedure allowing the overall approval of all phases of a drug’s clinical trials, replacing the phase-by-phase application and approval procedure, will be adopted for drugs’ clinical trial applications.

The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment. The Innovation Opinions indicated enhancing the standard of approval for drug marketing registration and accelerating the evaluation and approval process for innovative drugs as well as improving the approval of drug clinical trials.

The CFDA promulgated the Opinions on Encouraging the Priority Review and Approval for Drug Innovations (《關於鼓勵藥品創新實行優先審評審批的意見》) in December 2017, which further clarified that a fast track clinical trial approval or drug marketing registration pathway will be available to innovative drugs. The Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation was replaced by the Announcement of NMPA on Promulgating Three Documents including the Working Procedures for Evaluation of Breakthrough Therapy Designation Drugs (Trial) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》), which was issued and implemented on July 7, 2020, refined the requirements and scope of the fast track, and the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation was repealed simultaneously.

According to the Announcement on Matters Concerning the Optimization of 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 issued by the NMPA and the NHC in May 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

The Drug Registration Regulation has incorporated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduces four procedures for expedited marketing registration of drugs, which are procedures for groundbreaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval:

- Procedures for ground-breaking therapeutic drugs: during the drug clinical trials, for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approach, the applicant may request for application of procedures for ground-breaking therapeutic drugs.

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- Procedures for conditional approval: during the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, its benefits outweigh the risks according to the evaluation.
- Procedures for prioritized reviews and approval: at the time of the drug marketing registration, drugs have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drug, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drug included in the procedures for ground-breaking therapeutic drug; (v) drug which comply with conditional approval criteria; and (vi) other circumstances of prioritized review stipulated by the NMPA.
- Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency. Drug included in the special examination and approval procedures may, based on special needs of disease prevention and control, be restricted for use within a certain period and scope.

Communication with the CDE

According to the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) promulgated by the NMPA in July 2018, where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for Communication Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. Within 60 business days after the acceptance of and the fees paid for the clinical trial applications, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

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According to the Registration Measures, applicants could communicate with the CDE the key issues before applying for drug clinical trials, through the clinical trials, before applying for marketing authorization, or during other key stages. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), promulgated by the CDE on December 10, 2020, during the research and development periods and in the registration applications of drugs, the applicants may propose to conduct the communication session with the CDE. The communication session can be classified into three types. Type 1 meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type 2 meetings are held during the key research and development periods of drugs, mainly including meetings before the IND application, meetings upon the completion of Phase II trials and before the commencement of Phase III trials, meetings before submitting a marketing application for a new drug, and meetings for risk evaluation and control. Type 3 meetings refer to meetings not classified as Type 1 or Type 2.

Drug Manufacturing

According to the Drug Administration Law and the Regulations for Implementation of the Drug Administration Law of the PRC, a drug manufacturing enterprise is required to obtain a drug manufacturing license from the relevant provincial drug administration authority of the PRC. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Regulations of Implementation of the Drug Administration Law and the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) (the “GMP Rules”), promulgated in August 2004 and amended in November 2017 and January 2020, respectively, the drug manufacturing license is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. In addition, the name, legal representative, registered address and unified social credit code specified in the drug manufacturing certificate shall be identical to that set forth in the business license as approved and issued by the industrial and commercial administrative department. According to such measures, to the extent the MAH does not manufacture the drug but through contract manufacturing organization, the MAH shall apply for drug manufacturing license with the provincial counterpart of the NMPA, subject itself to inspections and other regulatory oversight by the agency.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) was promulgated in March 1988 and was amended in December 1992, June 1999 and January 2011. The Good Manufacturing Practice for Drugs comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

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Laws and Regulations Related to Vaccines

Vaccine Policies

The Laws on Prevention and Treatment of Infectious Diseases (《中華人民共和國傳染病防治法》), issued in February 1989 and amended in August 2004 and June 2013, stipulates that a planned prophylactic vaccination system is performed in the PRC. The health administration department under the State Council and such departments under the people’s governments of provinces, autonomous regions, and municipalities directly under the central government shall, in accordance with the requirements of prevention and control of infectious diseases, draw up plans for prophylactic vaccination against infectious diseases and coordinate efforts for their implementation. Vaccines used for prophylactic vaccination shall conform to the quality standards of the PRC.

According to the Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》) (the “**Vaccine Administration Law**”), which was promulgated by the SCNPC on June 29, 2019 and came into effect on December 1, 2019, the State applies the most stringent management system for vaccines, and adheres to the principles of safety first, risk management, whole-process control, scientific supervision and social co-governance. Also, a National Immunization Program system is applied in the PRC, under which the government would provide vaccines under the immunization program to the residents free of charge.

According to Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”), which was promulgated by the SCNPC on October 17, 2020 and came into effective on April 15, 2021, organizations engaged in biotechnology research and development shall comply with the national safety administration norms for biotechnology research and development. The high- or medium-risk biotechnology research and development activities shall be carried out by corporate bodies lawfully established within the territory of China and shall be approved or filed for record in accordance with the law. The corporate bodies engaged in high- or medium-risk biotechnology research and development activities shall conduct risk assessment, formulate risk prevention and control plans and emergency plans for biosafety incidents, and reduce the risks in the implementation of the research and development activities. The clinical research of new biomedical technologies shall pass the ethical review and be conducted in the medical institutions with corresponding qualifications; the operation of human clinical research shall be conducted by the professional medical workers with corresponding qualifications.

Vaccine Administration

On January 15, 2017, the General Office of State Council issued Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines (《關於進一步加強疫苗流通和預防接種管理工作的意見》) (the “**Vaccine Opinion**”) among others, to improve the mechanism for the management of vaccines and promote the independent R&D and quality improvement of vaccines. On June 29, 2019, the SCNPC released the Vaccine Administration Law, which requires the most stringent management system for vaccines, and at the same time,

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supports the basic research and applied research on vaccines and promotes the development and innovation of vaccines, including the development, production and reserve of vaccines for the prevention and control of serious diseases in the national strategy. Entities and individuals engaged in vaccine development, production, circulation and vaccination shall abide by the laws, regulations, rules, standards and specifications, ensure that the information during the whole process is true, accurate, complete and traceable, assume responsibilities in accordance with the law and accept social supervision.

Development and Registration of Vaccines

On October 14, 2005, the NMPA promulgated the Notice on Issuing Six Technical Guidelines including the Technical Guidelines on Preclinical Study of Preventive Vaccines (《關於印發<預防用疫苗臨床前研究技術指導原則>等6個技術指導原則的通知》), which specified the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

According to the Vaccine Administration Law, clinical trials of vaccines shall not be conducted without obtaining the approval of the drug administrative department under the State Council. Clinical trials of vaccines shall be conducted or organized for implementation by Grade III medical institutions that meet the conditions prescribed by the drug administrative department under the State Council and the competent health department under the State Council, or by disease prevention and control institutions at or above the provincial level.

A vaccine to be marketed within the territory of China shall be approved by the drug administrative department under the State Council and obtain a drug registration certificate; when applying for registration of a vaccine, an applicant shall provide true, sufficient and reliable data, information and samples.

According to the Vaccine Administration Law, for vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the NMPA shall prioritize the evaluation and approval work. With respect to a vaccine urgently needed for responding to a major public health emergency or any other vaccines urgently needed as determined by the health department under the State Council, if the benefits outweigh the risks upon assessment, the drug administrative department under the State Council may conditionally approve the vaccine registration application.

According to the Drug Registration Regulation, before the applicant submits an application for drug marketing authorization, it shall communicate with the CDE and, upon communication and confirmation, submit the application for drug marketing authorization and simultaneously submit an application for prioritized review and approval. Upon included in the procedures for prioritized review and approval, the sponsors could enjoy, among others, a shortened review period for drug marketing authorization within 130 days.

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Long Term Efficacy and Safety of Vaccines and Biological Products

On March 20, 2003, the CFDA promulgated the Notice on Issuing Nine Technical Guidelines (《關於印發<預防用以病毒為載體的活疫苗製劑的技術指導原則>等9個技術指導原則的通知》), including the Technical Guidelines on Preclinical Study of Preventive DNA Vaccines (《預防用DNA疫苗臨床前研究技術指導原則》), the Technical Guidelines on the Quality Control of Recombinant DNA Products (《人用重組DNA製品質量控制技術指導原則》), the Technical Guidelines on Gene Therapy and the Quality Control of Preparation. (《人基因治療研究和製劑質量控制技術指導原則》). On October 14, 2005, the CFDA promulgated the Notice on Issuing Six Technical Guidelines (《關於印發<預防用疫苗臨床前研究技術指導原則>等6個技術指導原則的通知》), including the Technical Guidelines on Preclinical Study of Preventive Vaccines (《預防用疫苗臨床前研究技術指導原則》), which is revised on April 12, 2010, the Technical Guidelines on the Management on the Change of Production Process of Biological Products (《生物製品生產工藝過程變更管理技術指導原則》), the Technical Guidelines on the Preclinical and Clinical Studies of Combined Vaccines (《聯合疫苗臨床前和臨床研究技術指導原則》), the Technical Guidelines on the Production and Quality Control of Polypeptide Vaccines (《多肽疫苗生產及質控技術指導原則》), the Technical Guidelines on the Quality Control and Clinical Research of Combined Vaccines (《結合疫苗質量控制和臨床研究技術指導原則》), the Guiding Principles on the Grading Standard for Adverse Reactions in Clinical Trials of Preventive Vaccines (《預防用疫苗臨床試驗不良反應分級標準指導原則》), which is revised on December 26, 2019. These Guidelines specify the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

On August 14, 2020, the CDE promulgated the Notice on Issuing Five Technical Guidelines for the Research and Development of COVID-19 Prophylactic Vaccines (for Trial Implementation) (《關於發布<新型冠狀病毒預防用疫苗研發技術指導原則(試行)>等5個指導原則的通知》), including the Technical Guidelines on research of COVID-19 Prophylactic Vaccines (for Trial Implementation) (《新型冠狀病毒預防用疫苗研發技術指導原則(試行)》), the Technical Guidelines on Pharmaceutical Research of COVID-19 Prophylactic mRNA Vaccines (for Trial Implementation) (《新型冠狀病毒預防用mRNA疫苗藥學研究技術指導原則(試行)》), the Technical Note for Non-clinical Validation Studies and Assessment of COVID-19 Prophylactic Vaccines (for Trial Implementation) (《新型冠狀病毒預防用疫苗非臨床有效性研究與評價技術要點(試行)》), the Technical Guidelines on Clinical Research of COVID-19 Prophylactic Vaccines (for Trial Implementation) (《新型冠狀病毒預防用疫苗臨床研究技術指導原則(試行)》), the Technical Guidelines on Clinical Assessment of COVID-19 Prophylactic Vaccines (for Trial Implementation) (《新型冠狀病毒預防用疫苗臨床評價指導原則(試行)》). These guidelines provide guidance, and referable technical standards for the clinical research and development of China’s COVID-19 vaccines.

REGULATORY OVERVIEW

Laws and Regulations Related to Oversea Listing

Foreign Investment

Since January 1, 2020, the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) promulgated by the National People’s Congress has come into effect. The Law of the People’s Republic of China on Sino-Foreign Equity Joint Ventures and the Law of the People’s Republic of China on Wholly Foreign-Owned and Law of the People’s Republic of China on Sino-Foreign Cooperative Joint Ventures were 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 favorable 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 (the “**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 MOFCOM on December 27, 2021, and came into effect on January 1, 2022 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 Ministry of Commerce. 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, 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, cancelation reports, and annual reports.

Overseas Securities Offering and Listing by Domestic Enterprises

On December 24, 2021, the CSRC promulgated the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(草案徵求意見稿)》), and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (the “**Draft Listing Measures**”, together with the Draft Listing Administrative Provisions, the “**New Draft Overseas Listing Rules**”), both of which had a comment period that expired on January 23, 2022.

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On February 17, 2023, after a year-long market consultation of the New Draft Overseas Listing Rules, the CSRC released the Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Trial Measures**”), together with five interpretative guidelines thereof, which became effective on March 31, 2023 (the “**Implementation Date**”). The Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities, and regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime. According to the Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC within three (3) working days after submitting the listing application documents to the overseas supervisory authorities and report relevant information.

On the same date, the CSRC also released the Notice on the Arrangements for the Filing Management of Overseas Listing of Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which stipulated that prior to the Implementation Date, the CSRC would carry on its works on a normal basis pursuant to relevant regulations for the accepted applications for administrative approval for the overseas securities listing, under which circumstance if such companies could not obtain administrative approval prior to the Implementation Date, these companies shall complete the filing procedures with the CSRC.

H-share Full Circulation

“Full circulation” means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued 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, 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 apply 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”. After the application for full circulation has been approved by the CSRC, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDC of the shares related to the application has been completed.

REGULATORY OVERVIEW

On December 31, 2019, CSDC and the Shenzhen Stock Exchange (“SZSE”) jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股“全流通”業務實施細則》) (the “**Measures for Implementation**”). The businesses in relation to the H-share full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

In order to fully promote the reform of H-share full circulation and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDC promulgated the Circular on Issuing the Guide to the Program for Full Circulation of H-shares (《H股“全流通”業務指南》) on February 7, 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, and other relevant matters. In February 2020, China Securities Depository and Clearing (Hong Kong) Limited also promulgated the Guide of China Securities Depository and Clearing (Hong Kong) Limited to the Program for Full Circulation of H-shares to specify the relevant escrow, custody, agent service, arrangement for settlement and delivery, risk management measures and other relevant matters.

According to the Measures for Implementation and the Guide to the Program for Full Circulation of H-shares, shareholders who apply for H Share Full Circulation (“**Participating Shareholders**”) shall complete the cross-border transfer registration for conversion of relevant domestic unlisted shares into H Shares before dealing in the shares, i.e., CSDC as the nominal shareholder, deposits the relevant securities held by Participating Shareholders at China Securities Depository and Clearing (Hong Kong) Limited (“**CSDC (Hong Kong)**”), and CSDC (Hong Kong) will then deposit the securities at HKSCC in its own name, and exercise the rights to the securities issuer through HKSCC, while HKSCC Nominees as the ultimate nominal shareholder is listed on the register of shareholders of H-share listed companies.

According to the Guide to the Program for Full Circulation of H-shares, H-share listed companies shall be authorized by Participating Shareholders to designate the only domestic securities company (“**Domestic Securities Company**”) to participate in the transaction of converted H shares. The specific procedure is as follows:

Participating Shareholders submit trading orders of the converted H Shares through the Domestic Securities Company, which transmits the orders to the Hong Kong Securities Company designated by the Domestic Securities Company through Shenzhen Securities Communications Co., Ltd.; and Hong Kong Securities Company conducts corresponding securities transactions in the Hong Kong market in accordance with the aforementioned trading orders and the rules of the Hong Kong Stock Exchange.

According to the Guide to the Program for Full Circulation of H-shares, upon the completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDC, CSDC and the Domestic Securities Company, and the Domestic Securities Company and the Participating Shareholders, will all be conducted separately.

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Laws and Regulations Related to Product Liability

Pursuant to the Product Quality Law (《中華人民共和國產品質量法》) promulgated on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively by SCNPC, Seller shall be responsible for the repair, replacement or return of the product sold if (1) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (2) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (3) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of purchased product, the seller shall compensate for such losses.

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 was amended on August 27, 2009 and October 25, 2013 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. Under the amendments made on October 25, 2013, all business operators must pay high attention to protecting customers' personal information and must strictly keep confidential any consumer information they obtain during their business operations.

Laws and Regulations Related to Environmental Protection and Fire Prevention

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

REGULATORY OVERVIEW

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction.

According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Pollutant Discharge Licensing

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) (《排污許可管理辦法(試行)》) promulgated on January 10, 2018 and partially revised on August 22, 2019 by the Ministry of Ecology and Environment, or the MEE, enterprises and public institutions as well as other producers and operators included in the Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources shall apply for and obtain a pollutant discharge license within a prescribed time limit. Any enterprise that fails to obtain a pollutant discharge license as required shall not discharge pollutants.

According to the Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the MEE on December 20, 2019, key management, simplified management and registration management of pollutant discharge permits are implemented according to factors such as the amount of pollutants generated, the amount of emissions, the degree of impact on the environment, etc., and only pollutant discharge entities that implement registration management do not need to apply for a pollutant discharge permit.

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The State Council issued the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》) on January 24, 2021 to further enhance the pollutant discharge administration. The administration on pollutant discharge units are divided into key management and simplified management pursuant to the amount of pollutant caused and discharged and the impact on the environment. The review, decision and information disclosure of pollutant discharge licenses shall be handled through the national pollutant discharge license management information platform. The pollutant discharge license is valid for 5 years and the discharging units should apply for renewal 60 days before the expiry for continues pollutant discharge.

Acceptance Inspection on Environmental Protection Facilities

Interim Measures for Acceptance inspection of Environmental Protection upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

Fire Prevention Design and Acceptance

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the “**Fire Prevention Law**”), was issued on April 29, 1998, then became effective on September 1, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

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Laws and Regulations Related to Intellectual Property

Patent

The Patent Law of the People’s Republic of China (《中華人民共和國專利法》) (the “**Patent Law**”) is revised by the SCNPC on October 17, 2020 and came into effect on June 1, 2021. According to the current Patent Law, when the invention or utility model patent is granted, unless otherwise stipulated in the Patent Law, without the approval of the patent owner, no entity or person shall implement the relevant patent, that is, manufacture, use, offer to sell, sell or import the patented products for business purpose, or use the patented method and use, offer to sell, sell or import the products directly obtained with the patented method. Implementing the patent without the approval of the patent owner constitutes the infringement of patent rights. Any dispute in connection with this shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the patent owner or the relevant stakeholders may file a lawsuit in the people’s court or turn to the patent administration authorities for handling.

Pursuant to the Rules for Implementation of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則》), which was amended by the State Council on 9 January 2010 and became effective on 1 February 2010, where the entity to which a patent right is granted fails to agree with the inventor or the designer on, or to specify in its legitimately enacted company rules the way and amount of reward and remuneration specified in its rules and regulations established by law, the entity shall reward to the inventor or designer within 3 months after the announcement of granting the patent. The minimum reward for one invention patent shall not be less than RMB3,000; and the minimum reward for one utility model or design patent shall not be less than RMB1,000. The entity shall, after exploiting the patent for invention-creation within the term of the patent right, pay the inventor or designer remuneration at a percentage of not less than 2% each year from the profits generated from the exploitation of the invention or utility model patent, or at a percentage of not less than 0.2% from the profits gained from the exploitation of the design, or pay the inventor or creator a lump sum of remuneration by reference to the above percentages; where the entity to which a patent right is granted authorize other entity or individual to exploit its patent, it shall reward the inventor or designer at a percentage no less than 10% from the license and royalty fee.

Trademark

According to the Trademark Law of the People’s Republic of China (《中華人民共和國商標法》) revised by the SCNPC on April 23, 2019 and taking effect on November 1, 2019 (the “**Trademark Law**”), the registered trademark has a validity period of 10 years starting from the registration date. The trademark registrant enjoys the exclusive right to use the trademark. Any dispute in connection with the activities the infringe the exclusive right to use a registered trademark set out in Article 57 of the Trademark Law shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the trademark registrant or the relevant stakeholders may file a lawsuit in the people’s court or turn to the industrial and commercial administrative department for handling.

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Copyright

Copyright is protected by the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the SCNPC on September 7, 1990 and last amended on November 11, 2020 and effective from June 1, 2021 and the Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》) issued by the State Council on August 2, 2002 and last amended on January 30, 2013, which provided provisions on the classification of works and the obtaining and protection of copyright and the related rights.

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Information Industry is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register”. A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019 respectively and the Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement (《最高人民法院關於審理侵犯商業秘密民事案件適用法律若干問題的規定》) issued by the Supreme People’s Court on September 10, 2020 and effective from September 12, 2020, the term “trade secrets” refers to technical, operational and other business information that is unknown to the public, has business value, may create business interests or profits for its legal owners or holders, and is maintained as a secret with relevant security measures taken by its right holders. According to the Anti-Unfair Competition Law of the PRC, business operators are prohibited from infringing others’ trade secrets by (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (ii) disclosing, using or allowing other person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph; (iii) disclosing, using or allowing other person to use a trade secret in its possession in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting, tempting or aiding a person into or in acquiring, disclosing, using or allowing other person to use the trade secret of the right holder in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known the abovementioned illegal conducts but nevertheless acquires,

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uses or allows other persons to use such trade secrets, the third party shall be deemed to have infringed others’ trade secrets. The right holders whose trade secrets are infringed may apply for administrative corrections, and the regulatory authorities shall order to stop any illegal activities and impose fine penalties on the infringers.

Information Security and Data Privacy

Pursuant to the PRC Civil Code (《中華人民共和國民法典》), the personal information of a natural person shall be protected by the law. An information processor shall not disclose or tamper with any personal information collected or stored thereby; and without the consent of the natural person, no personal information shall be illegally provided to any other person, excluding the information through which the specific individual cannot be identified after processing and which cannot be restored. An information processor shall take technical measures and other necessary measures to ensure the security of the personal information collected and stored thereby and prevent information leakage, tampering, and loss.

On May 8, 2017, the Supreme People’s Court and the Supreme People’s Procuratorate jointly released the Interpretations of the Supreme People’s Court and the Supreme People’s Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens’ Personal Information (《最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋》) (the “**Interpretations**”), which came into effect on June 1, 2017, clarifies several concepts regarding the crime of “infringement of citizens’ personal information” stipulated by Article 253A of the Criminal Law of the PRC (《中華人民共和國刑法》), including the “provision of citizens’ personal information” and “illegally obtaining any citizen’s personal information by other methods”. In addition, the Interpretations specify the standards for determining “serious circumstances” and “particularly serious circumstances” of this crime.

The Data Security Law of the PRC (《中華人民共和國數據安全法》), which was promulgated by the SCNPC on June 10, 2021 and took effect on September 1, 2021, provides that China shall establish a data classification and grading protection system, formulate the important data catalogs to enhance the protection of important data. Processors of important data shall specify the person responsible for data security and management agencies to implement data security protection responsibilities. Relevant authorities will establish the measures for the cross-border transfer of important data. If any company violates the Data Security Law of the PRC to provide important data outside China, such company may be punished by administration sanctions, including penalties, fines, and/or suspension of relevant business or revocation of the business license.

The Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》), which were issued by the General Office of the State Council and another authority on July 6, 2021, require to speed up the revision of legislation on strengthening the confidentiality and archives coordination between regulators related to overseas issuance and listing of securities, and improvement to the legislation on data security, cross-border data flow, and management of confidential information.

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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**”) was promulgated by the SCNPC on August 20, 2021 and came into effect on November 1, 2021. The Personal Information Protection Law reiterates the circumstances under which a personal information processor could process personal information and the requirements for such circumstances, such as when (1) the individual’s consent has been obtained; (2) the processing is necessary for the conclusion or performance of a contract to which the individual is a party; (3) the processing is necessary to fulfill statutory duties and statutory obligations; (4) the processing is necessary to respond to public health emergencies or protect natural persons’ life, health and property safety under emergency circumstances; (5) the personal information that has been made public is processed within a reasonable scope in accordance with this Law; (6) personal information is processed within a reasonable scope to conduct news reporting, public opinion-based supervision, and other activities in the public interest; or (7) under any other circumstance as provided by any law or regulation. It also stipulates the obligations of a personal information processor. Any violation of the provisions and requirements under the Personal Information Protection Law may subject a personal information processor to rectifications, warnings, fines, suspension of the related business, revocation of licenses, being entered into the relevant credit record or even criminal liabilities.

Laws and Regulations Related to Employment and Social Securities

Employment

According to the Labor Law of the People’s Republic of China (《中華人民共和國勞動法》) taking effect on January 1, 1995 and revised on December 29, 2018 and the Labor Contract Law of the People’s Republic of China (《中華人民共和國勞動合同法》) taking effect on January 1, 2008 and revised on December 28, 2012, a labor contract shall be signed when the employer establishes labor relationship with the worker. The labor contracts shall be signed in written. When agreement is reached after negotiation, labor contracts, including fixed term labor contract, open term labor contract or labor contract based on the completion of work, shall be signed, and the salary shall be no less than the local minimum wage standard. The employer and the worker shall each fully perform its/his obligations in accordance with the labor contract.

Social Securities

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time

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limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5‰ shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department.

Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day and was recently revised on March 24, 2019) prescribes the details concerning the social securities.

Housing Provident Fund

According to Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) issued by the State Council on April 3, 1999 and revised and implemented on March 24, 2019, the enterprises shall fully pay the housing provident fund contribution for the employees on time, with the contribution ratio no less than 5% of the average monthly salary of the relevant employee in the previous year. The housing provident fund contribution paid by the employees and the employers shall be owned by the employees.

Laws and Regulations Related to Tax

Enterprise Income Tax

According to the Corporate Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》), which was promulgated on March 16, 2007, came into effect on January 1, 2008 and amended by the SCNPC on February 24, 2017 and December 29, 2018, and Implementation Regulations for the Corporate Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and amended by the State Council on April 23, 2019 and came into effect on the same date, all the domestic enterprises in China (including foreign-invested enterprises) shall be subject to enterprise income tax at the uniform tax rate of 25%, except for the high-tech enterprises certificated by the state, which will be subject to enterprise income tax at the reduced rate of 15%, or the qualified small low-profit enterprises, which will enjoy the reduced enterprise income tax rate of 20%.

Value-added Tax

The Provisional Regulations on Value-added Tax of the People’s Republic of China (《中華人民共和國增值稅暫行條例》), which was promulgated on December 13, 1993, came into effect on January 1, 1994, and last amended on November 19, 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the People’s Republic of China (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated

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on December 25, 1993 and came into effective on the same date, and was amended on December 15, 2008 and October 28, 2011, came into effect on November 1, 2011 set out that all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated. According to the Notice of the Ministry of Finance and the SAT on Adjusting Value added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the Ministry of Finance, the SAT and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the VAT rate was reduced to 13% and 9%, respectively.

Laws and Regulations Related to Foreign Exchange

The Regulations on Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) issued by the State Council on January 29, 1996 and implemented on April 1, 1996, which was revised on January 14, 1997 and August 5, 2008 respectively, is the key foreign exchange control regulation in force, applicable to the foreign exchange income and payment and foreign exchange operation activities of the domestic institutions and domestic individuals in China and the foreign exchange payment and collection and foreign exchange operation activities of the overseas institutions and overseas individuals in China.

The Regulations on Foreign Exchange Settlement, Sale and Payment (《結匯、售匯及付匯管理規定》) issued by PBOC on June 20, 1996 and implemented on July 1, 1996 set out requirements on the foreign exchange settlement, purchase, payment, opening of foreign exchange account and external payment by the domestic institutions, individual citizens, foreign institutions in China and foreigners in China.

According to the Decision of the State Council on Canceling and Adjusting A Batch of Items Requiring Administrative Approval (《國務院關於取消和調整一批行政審批項目等事項的決定》) issued by the State Council on October 23, 2014, SAFE and its branches canceled the review and approval on the foreign exchange settlement for the repatriation of funds raised abroad under the overseas listed foreign capital stock account.

In addition, according to the Notice of SAFE on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listing with the foreign exchange control bureau located at its registered address in 15 working days after the completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

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According to the Notice of SAFE on Reforming and Standardizing Capital Account Foreign Exchange Settlement Administration Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) issued by SAFE on June 9, 2016, it has been specified clearly in the relevant policies that, for the capital account foreign exchange income subject to voluntary foreign exchange settlement (including the repatriation of the proceeds from overseas listing), the domestic institutions may conduct the foreign exchange settlement at the banks according to their operation needs. The proportion of the capital account foreign exchange income subject to voluntary foreign exchange settlement was tentatively set as 100%, provided that SAFE may adjust the aforesaid proportion according to the international payment balance status in good time.

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.

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 implemented 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.

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 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.

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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 (the “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 re-approve 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 I, Phase II and Phase III, and may overlap.

- Phase I 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 II 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 III 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 the 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 usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with 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.

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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, 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 IV 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.

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Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Fast Track Designation

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address medical needs for the disease or condition. Under the fast track program, the sponsor of a drug candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast track designation determination within 60 days after receipt of the sponsor’s request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a fast track product’s NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA’s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

As of the Latest Practicable Date, none of our drug candidates had obtained the fast track designation.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (the “PDUFA”) guidelines. These six- and ten- month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

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Accelerated Approval

Under the 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 (the “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, will allow the FDA 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 circumstance.

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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 (the “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 noncompliance 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. 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.

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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 adverse events 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 in March 2010, and has driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare is financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA 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 the 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. Since January 2017, former President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, 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

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enacted by the Congress in 2017 that 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, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. There may be other efforts to challenge, repeal or replace the ACA.

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 United States Patent and Trademark Office (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.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

We are a biotechnology company dedicated to developing BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases.

Our history can be traced back to the establishment of Wuhan YZY Biopharma Limited Company (武漢友芝友生物製藥有限公司) on July 8, 2010, the predecessor of the Company prior to its conversion into a joint stock company under the laws of the PRC. On January 13, 2022, pursuant to the promoters’ agreement among the then Shareholders, the Company was converted into a joint stock limited liability company with its corporate name changed to Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司). As of the Latest Practicable Date, the registered capital of the Company was RMB182,000,000, divided into 182,000,000 Shares, with a nominal value of RMB1.00 each.

MILESTONES

The following sets out a summary of our key development milestones since our inception:

Year	Milestone(s)
July 2010	The predecessor of the Company, Wuhan YZY Biopharma Limited Company (武漢友芝友生物製藥有限公司) was established
	The initiation of BsAb platform development
May 2012	Established a GMP-compliant quality system
November 2012	The initiation of M802 R&D
	The filing of the PCT patent application “Bispecific antibody” for the protection of the YBODY [®] platform
July 2013	The initiation of M701 R&D
December 2013	The determination of molecule structure of M802 and M701
June 2014	Novel Bispecific Antibody Drugs for the Treatment of Tumors Development Project (“新型腫瘤治療性雙特異性抗體藥物開發課題”) selected for the Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) under the Twelfth Five-year Plan
September 2015	M701 selected for the Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) under the Twelfth Five-year Plan
April 2016	M802 became the first BsAb to file IND application in China

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Year	Milestone(s)
August 2016	Completed Series Pre-A Financing ⁽¹⁾ and raised an aggregate amount of approximately RMB50 million
February 2017	Patent protection for our YBODY [®] platform in U.S. expanded to cover 35 targets M701 became the second BsAb to file IND application in China
September 2017	Obtained NMPA IND approval for our clinical investigation of M802 in China, which is China’s first IND approval for self-developed BsAb
February 2018	Obtained NMPA IND approval for our clinical investigation of M701 in China, which is China’s second IND approval for self-developed BsAb
March 2018	The establishment of the Check-BODY platform
April 2018	Completed Series A Financing ⁽¹⁾ and raised an aggregate amount of approximately RMB157.2 million
December 2018	Patent issued for the protection of M802 in China Patent issued for the protection of our YBODY [®] platform in CD3 and HER2 targets in U.S. The establishment of the Nano-YBODY [™] platform
July 2019	PCT patent application for the protection of our Check-BODY platform was filed
August 2019	Obtained FDA IND approval for our clinical investigation of M802 in U.S.
October 2019	Obtained FDA IND approval for our clinical investigation of M701 in U.S.
February 2020	The establishment of the UVAX [®] platform
August 2020	Obtained FDA IND approval for our clinical investigation of Y150 in U.S.
January 2021	Completed Series B Financing ⁽¹⁾ and raised an aggregate amount of approximately RMB168.7 million Obtained NMPA IND approval for our clinical investigation of Y150 in rrMM in China

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone(s)
February 2021	Completed Series B+ Financing ⁽¹⁾ and raised an aggregate amount of approximately RMB20 million
May 2021	Obtained NMPA IND approval for our clinical investigation of Y101D in metastatic or locally advanced solid tumors in China
August 2021	Completed Series B++ Financing ⁽¹⁾ and raised an aggregate amount of approximately RMB73.5 million
December 2021	Obtained NMPA IND approval for our clinical investigation of Y2019 in China Initiated a Phase II clinical trial for M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China
January 2022	The Company was converted into a joint stock limited company with its corporate name changed to “Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司)”
July 2022	Obtained IND approval for a Phase Ib/II clinical trial of M701 for the treatment of MPE in China Entered into asset transfer agreement with CMS Vision for Y400
October 2022	Completed Series C Financing ⁽¹⁾ and raised an aggregate amount of approximately RMB200 million
December 2022	Obtained the IND approval for a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for pancreatic cancer patients in China Obtained IND approval for a Phase Ib/II clinical trial of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China
April 2023	Obtained IND approval for Y332 for metastatic or locally advanced solid tumors Obtained IND approval for Y400 for wAMD and DME

(1) Completion of relevant rounds of financing of the Company refers to the completion of the industrial and commercial registration.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR SUBSIDIARIES

The following table sets out certain information of our three subsidiaries as of the Latest Practicable Date:

Subsidiaries	Date and place of establishment	Registered capital	Equity interest attributable to our Group	Principal activities
Shijiazhuang Shiyong	April 21, 2020; PRC	RMB1,000,000	100%	Investment vehicle with no substantial business operation
Nanjing Youbodi	December 29, 2020; PRC	RMB20,000,000	100%	Investment vehicle with no substantial business operation
Wuhan Youwei	March 22, 2021; PRC	RMB1,000,000	100%	R&D (including clinical development) of vaccine

ESTABLISHMENT AND CORPORATE DEVELOPMENT

Establishment and Major Shareholding Changes in the Company Prior to 2016

On July 8, 2010, the predecessor of the Company, Wuhan YZY Biopharma Limited Company (武漢友芝友生物製藥有限公司), was established under the laws of the PRC with a registered capital of RMB50,000,000 by Yuan Qian, Guangdong Huakai Investment Co., Ltd. (廣東鐸凱投資有限公司) (“**Huakai Investment**”, a limited liability company established in the PRC on June 7, 2007), Dr. Zhou Hongfeng and Ou Jinglan (mother of Dr. Zhou Pengfei), holding 60.00%, 19.00%, 11.00% and 10.00% of the Company’s then registered capital, respectively. At the time of the establishment of the predecessor of the Company, Huakai Investment was owned as to 35.00% by Dr. Zhou Hongfeng (also then a director of Huakai Investment) and as to 65.00% by three other individual shareholders. The three individual shareholders respectively held 38.00%, 18.00% and 9.00% of the registered capital of Huakai Investment and were independent third parties. In addition, Huakai Investment and the aforesaid three individual shareholders were also independent from Dr. Zhou Pengfei, Yuan Qian and Ou Jinglan. Dr. Zhou Hongfeng saw the great potential of the Company’s business and convinced the other shareholders of Huakai Investment to invest in the Company. On the other hand, Yuan Qian, Dr. Zhou Hongfeng and Dr. Zhou Pengfei (collectively, the “**Founders**”) are alumni of Tongji Medical College of Huazhong University of Science and

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Technology (華中科技大學同濟醫學院) and became acquainted with each other by then. Ou Jinglan, through her son, Dr. Zhou Pengfei, also became acquainted with Yuan Qian and Dr. Zhou Hongfeng. After graduation, Yuan Qian started his own business and obtained substantial investment experience; Dr. Zhou Hongfeng first served as a university teacher and then mainly engaged in operation affairs in the medical industry; and Dr. Zhou Pengfei obtained rich clinical and management experience through studying abroad and working in a large pharmaceutical company. For details, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Directors” in this document. The Founders had insight into the strong market demand in the domestic pharmaceutical industry and emerged with the vision of discovering and developing innovative drugs for healthier lives of patients. With a view to exploring the potential of the industry, they decided to establish a biotechnology company that is dedicated to developing BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. To facilitate the Company’s establishment, Dr. Zhou Pengfei sought financial support from Ou Jinglan, who contributed 10.00% of the Company’s then registered capital and owned corresponding equity interest.

On April 10, 2014, Huakai Investment transferred 19% of the equity interest in the Company to Dr. Zhou Hongfeng at a consideration of RMB9,500,000, reflecting the amount of registered capital of the Company being transferred. After such equity transfer, the Company was owned by Yuan Qian, Dr. Zhou Hongfeng and Ou Jinglan as to 60.00%, 30.00% and 10.00%, respectively.

On April 16, 2014, the registered capital of the Company was increased from RMB50,000,000 to RMB100,000,000 and Yuan Qian, Dr. Zhou Hongfeng and Ou Jinglan contributed RMB30,000,000, RMB15,000,000 and RMB5,000,000, respectively, reflecting their then respective equity interest percentage in the Company.

On December 2, 2015, Yuan Qian, Dr. Zhou Hongfeng and Ou Jinglan transferred 4.8%, 2.4% and 0.8% of the equity interest in the Company, respectively, to Wuhan Caizhi, a limited partnership established on September 21, 2015, as an employee incentive platform of the Company, at the cash consideration of RMB4,800,000, RMB2,400,000 and RMB800,000, respectively, reflecting the amount of registered capital of the Company being transferred. For more details on the employee incentive platforms of the Company, please refer to the paragraphs headed “– Employee Incentive Platforms” in this section. Immediately after the above-mentioned equity transfer, the Company was owned by Yuan Qian, Dr. Zhou Hongfeng, Ou Jinglan and Wuhan Caizhi as to 55.20%, 27.60%, 9.20% and 8.00%, respectively.

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Series Pre-A Financing

Pursuant to the capital contribution agreement dated February 2, 2016, the registered capital of the Company was increased from RMB100,000,000 to RMB110,000,000, and the following series pre-A financing investors, both of which were independent third parties, agreed to subscribe the increased registered capital of RMB10,000,000 of the Company at an aggregate consideration of RMB50,000,000 (the “**Series Pre-A Financing**”). The consideration of the Series Pre-A Financing was determined based on arm’s length negotiations among the relevant parties taking into account the then development of the Company’s drug candidates. The respective subscription amount in the registered capital of the Company and consideration paid by the subscribers in the Series Pre-A Financing were as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration paid (RMB)
Ningbo Panlin Qianyuan Equity Investment Partnership (Limited Partnership) (寧波磐霖仟 源股權投資合夥企業(有限合夥)) (“ Panlin Qianyuan ”)	6,000,000	30,000,000
Beijing Shengnuoji Pharmaceutical Technology Co., Ltd (北京盛諾基醫藥科技有限公司) (“ Beijing Shengnuoji ”)	4,000,000	20,000,000
Total	10,000,000	50,000,000

Upon the completion of the Series Pre-A Financing, the Company was owned by Yuan Qian, Dr. Zhou Hongfeng, Ou Jinglan, Wuhan Caizhi, Panlin Qianyuan and Beijing Shengnuoji as to approximately 50.18%, 25.09%, 8.36%, 7.27%, 5.45% and 3.64%, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Equity Transfers in 2016 and 2017

After the completion of the Series Pre-A Financing and prior to the Series A Financing (as defined below), there were three rounds of equity transfers, the details of which were set out as follows:

Date of the equity transfer agreements	Transferees	Transferors	Registered capital acquired (RMB)	Consideration (RMB)	Basis of consideration
September 1, 2016	Dr. Zhou Pengfei	Ou Jinglan (mother of Dr. Zhou Pengfei)	9,200,000	9,200,000	reflecting the amount of registered capital of the Company being transferred
November 29, 2016	Yuan Qian	Panlin Qianyuan	3,312,000	17,043,643	determined based on arm's length
	Dr. Zhou Hongfeng		1,656,000	8,521,822	negotiations among the relevant parties taking
	Dr. Zhou Pengfei		552,000	2,840,607	into account the previous investment
	Wuhan Caizhi		480,000	2,470,093	costs of Panlin Qianyuan
July 12, 2017	Wuhan Caizhi	Yuan Qian	4,812,000	5,941,284.02	determined based on all
		Dr. Zhou Hongfeng	2,406,000	2,970,642.01	the previous
		Dr. Zhou Pengfei	802,000	990,214	investment costs of Yuan Qian, Dr. Zhou Hongfeng and Dr. Zhou Pengfei, taking into account that Wuhan Caizhi is an employee incentive platform of the Company

The above three rounds of equity transfers in 2016 and 2017 were fully settled on August 1, 2019 and upon the completion of the three rounds of equity transfers in 2016 and 2017, the Company was owned by Yuan Qian, Dr. Zhou Hongfeng, Wuhan Caizhi, Dr. Zhou Pengfei and Beijing Shengnuoji as to approximately 48.82%, 24.41%, 15.00%, 8.14% and 3.64%, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Series A Financing

The Company underwent series A financing in 2018 through capital increase and equity transfers (the “**Series A Financing**”). In 2017, CSPC was introduced to the Founders as a potential investor. As confirmed by CSPC-NBP, it was confident in the Company’s business and drug candidates and felt optimistic about the Company’s future prospects considering the Company’s visionary, seasoned and execution-driven management and R&D teams. On the other hand, by virtue of CSPC being a well-known pharmaceutical company listed on the Stock Exchange and CSPC Group having comprehensive and quality resources for clinical trials and product commercialization, the Founders decided to introduce CSPC-NBP, a wholly-owned subsidiary of CSPC, as a shareholder to facilitate the Company’s future development.

Subscription of increased registered capital in Series A Financing

Pursuant to the capital contribution agreement dated January 9, 2018 entered into among the Series A Financing investors set forth below and our then Shareholders, the registered capital of the Company was increased from RMB110,000,000 to RMB141,428,600, and the following Series A Financing investors agreed to subscribe the increased registered capital of the Company in a total amount of RMB31,428,600 at an aggregate consideration of RMB157,200,000. The respective subscription amount in the registered capital of the Company and consideration paid by the subscribers in the Series A Financing were set out as follow:

Subscribers	Registered capital subscribed for (RMB)	Consideration (RMB)
CSPC-NBP	15,242,900	76,242,000
Shijiazhuang Shidai Weiye Cultural Development Co., Ltd (石家莊市時代偉業文化發展有限公司) (“ Shidai Weiye ”) ⁽¹⁾	8,328,600	41,658,000
Ningbo Meishan Bonded Port Area Guangrui Hongxiang Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區廣瑞弘祥股權投資合夥企業(有限合夥)) (“ Guangrui Hongxiang ”)	7,857,100	39,300,000
Total	31,428,600	157,200,000

(1) Pursuant to an equity transfer agreement dated January 8, 2021 entered into between Shidai Weiye and Hainan Boyou Enterprise Management Consulting Center (Limited Partnership) (海南博友企業管理諮詢中心(有限合夥)) (“**Hainan Boyou**”), Shidai Weiye transferred the entire equity interest it held in the Company to Hainan Boyou at an aggregate consideration of RMB53,000,000, reflecting previous contributions made by Shidai Weiye in the Company (namely, RMB41.658 million paid in the Series A Financing and RMB11.342 million paid in the Additional Consideration (as defined below)). At the time of the equity transfer, Shidai Weiye was owned as to 60% and controlled by Liu Dong (劉東) (also being the general partner of Hainan Boyou). The equity transfer was conducted for the internal restructuring purpose between Shidai Weiye and Hainan Boyou, both ultimately beneficially owned or controlled by Liu Dong. The equity transfer was settled on January 19, 2021.

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Pursuant to a supplemental agreement to the capital contribution agreement dated January 9, 2018 (the “**Supplemental Agreement**”), CSPC-NBP, Shidai Weiye and Guangrui Hongxiang agreed to further contribute a total of RMB42.8 million (namely, RMB20.758 million from CSPC-NBP, RMB11.342 million from Shidai Weiye and RMB10.70 million from Guangrui Hongxiang) in addition to the consideration payable by them in the Series A Financing (i.e. RMB157,200,000) as contingent consideration for the Company to complete certain milestones as set forth below:

Milestones	Contingent consideration payable by CSPC-NBP, Shidai Weiye and Guangrui Hongxiang upon the completion of relevant milestones
To obtain IND approval for M701 and domestic patent rights for the preparation and utilization of M701 and M802 by December 31, 2018 (“ 2018 Milestone ”)	RMB10 million (i.e., RMB4.85 million by CSPC-NBP, RMB2.5 million by Guangrui Hongxiang and RMB2.65 million by Shidai Weiye)
To receive FDA’s acceptances of the IND applications for M701 and M802 by December 31, 2019 (“ 2019 Milestone ”)	RMB14 million (i.e., RMB6.79 million by CSPC-NBP, RMB3.5 million by Guangrui Hongxiang and RMB3.71 million by Shidai Weiye)
To receive NMPA’s acceptance of the IND applications for two new drug candidates and to file the relevant patent applications to the USPTO or the CNIPA by December 31, 2020 (“ 2020 Milestone ”)	RMB18.8 million (i.e., RMB9.118 million by CSPC-NBP, RMB4.7 million by Guangrui Hongxiang and RMB4.982 million by Shidai Weiye)

The Company has successfully completed 2018 Milestone and 2019 Milestone and the contingent consideration payable thereunder in a total of RMB24 million was fully settled in cash in January and December 2019, respectively. The Company failed to complete 2020 Milestone in time by December 31, 2020 due to the outbreak of COVID-19 and therefore the contingent consideration thereunder in a total of RMB18.8 million was not paid by CSPC-NBP, Shidai Weiye and Guangrui Hongxiang pursuant to the terms and conditions of Supplemental Agreement.

However, soon in February 2021, the Company achieved 2020 Milestone. The Company further negotiated with CSPC-NBP, Shidai Weiye and Guangrui Hongxiang and they agreed to contribute a total of RMB18.8 million to the Company as in following manner: (i) RMB14.1 million by CSPC-NBP and Shidai Weiye by way of setting off debt of the Company due to CSPC-NBP and Shidai Weiye, respectively, and (ii) RMB4.7 million by Guangrui Hongxiang in cash on March 26, 2021 (collectively, the “**March 2021 Contributions**”). As of March 26, 2021, the contingent consideration payable upon the completion of 2018 Milestone and 2019 Milestone in a total of RMB24 million and the further contribution in a total of RMB18.8

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million under the March 2021 Contributions from CSPC-NBP, Shidai Weiye and Guangrui Hongxiang (the “**Additional Consideration**”) was all settled. The non-completion of the 2020 Milestone in time had minimum impact on the Company’s financial positions and no impact on its R&D.

The RMB14.1 million debt of the Company due to CSPC-NBP and Shidai Weiye was incurred under an unsecured loan agreement entered into among the Company, CSPC-NBP and Shidai Weiye on February 17, 2020 in the amount of RMB14.1 million with a fixed interest rate of 8% per annum (the “**Loan Agreement**”). The purpose of the Loan Agreement was to ensure the Company had sufficient working capital to fund its R&D activities before the Company received the proceeds from the Series B Financing. Pursuant to the arm’s length negotiations among the parties, CSPC-NBP and Shidai Weiye agreed to waive the principal amount of RMB14.1 million of the loan under the Loan Agreement. After the aforesaid waiver of RMB14.1 million loan, the Company was obliged to repay the interests of the loan of RMB1.195 million, which was all paid in full by the Company as at the Latest Practicable Date.

Equity transfer in Series A Financing

Pursuant to the equity transfer agreements dated January 10, 2018 and March 22, 2018 entered into among the Series A Financing investors and our then Shareholders set forth below, the following Series A Financing investors agreed to acquire registered capital of the Company in a total amount of RMB49,342,800 at an aggregate consideration of RMB246,804,000 from the then Shareholders. The respective transfer amount in the registered capital of the Company and consideration paid by the Series A Financing investors were set out as follows:

<u>Date of the equity transfer agreements</u>	<u>Transferees</u>	<u>Transferors</u>	<u>Registered capital acquired</u> (RMB)	<u>Consideration</u> (RMB)
January 10, 2018	CSPC-NBP	Yuan Qian	25,663,000	128,361,660
		Dr. Zhou	12,837,000	64,208,340
		Hongfeng		
		Dr. Zhou	2,200,000	11,004,000
March 22, 2018	Long Star Growth Group Limited (長星成長集團有限公司) (“ Long Star Growth ”)	Pengfei		
		Yuan Qian	5,761,900	28,820,000
		Dr. Zhou	2,880,900	14,410,000
		Hongfeng		

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of the Series A Financing, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Dr. Zhou Hongfeng, Long Star Growth, Shidai Weiye (subsequently transferred to Hainan Boyou), Guangrui Hongxiang, Dr. Zhou Pengfei and Beijing Shengnuoji as to approximately 39.56%, 15.75%, 11.67%, 7.87%, 6.11%, 5.89%, 5.56%, 4.77% and 2.83%, respectively. In view of the Company’s obtaining the clinical trial approvals for M802 and M701 and having standardized management operations and promising development prospects, CSPC-NBP intended to enhance its influence and promote business synergy with the Company. Pursuant to the memorandums of understanding dated January 10, 2018 entered into between CSPC-NBP and each of Shidai Weiye and Guoxin Sichuang Investment Fund Management (Beijing) Co., Ltd (國新思創投資基金管理(北京)有限公司) (“**Guoxin Sichuang**”) (the general partner of Guangrui Hongxiang), respectively, and a concert party agreement dated March 22, 2018 entered into between CSPC-NBP and Long Star Growth, Long Star Growth, Shidai Weiye and Guoxin Sichuang agreed to act in concert with CSPC-NBP and reach consensus on proposals presented to general meetings of the Company for voting (“**CSPC-NBP Concert Party Arrangements**”) and the Company was therefore accounted as a subsidiary of CSPC-NBP since January 2018. As the Company continued to grow and make new business progress (including but not limited to developing the Check-BODY platform and Nano-YBODY™ platform, as well as initiating the R&D of two important drug candidates, namely Y150 and Y101D), the Company started the Series B Financing (as defined below) in 2020 to introduce several new investors. To support the independent development of the Company and to provide more flexibilities for the management team and R&D team to fully exploit their expertise in the relevant field, parties to the CSPC-NBP Concert Party Arrangements mutually agreed to terminate the CSPC-NBP Concert Party Arrangements, which, in their view, is in the best interests of the Company and the Shareholders. Pursuant to the agreements dated April 1, 2020 entered into between CSPC-NBP and each of Shidai Weiye and Guangrui Hongxiang, respectively, and a confirmation letter dated December 7, 2021 executed by CSPC-NBP and Long Star Growth, CSPC-NBP, Long Star Growth, Shidai Weiye and Guoxin Sichuang agreed to terminate such CSPC-NBP Concert Party Arrangements and the Company therefore ceased to be a subsidiary of CSPC-NBP with effect from April 1, 2020.

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Equity Transfer in 2020

Pursuant to the equity transfer agreement dated August 17, 2020 entered into among Zhongheng Tongde (as defined below), Dr. Guo Hongwei and Beijing Shengnuoji, Zhongheng Tongde and Dr. Guo Hongwei agreed to acquire registered capital of the Company in a total amount of RMB4,000,000 at an aggregate consideration of RMB33,000,000 from Beijing Shengnuoji. The respective transfer amount in the registered capital of the Company and consideration paid by Zhongheng Tongde and Dr. Guo Hongwei were set out as follows:

Transferees	Transferors	Registered capital acquired (RMB)	Consideration (RMB)
Nanning Zhongheng Tongde Pharmaceutical Industry Investment Fund Partnership (Limited Partnership) (南寧中恒同德 醫藥產業投資基金合夥企業 (有限合夥)) (“Zhongheng Tongde”)		3,636,364	30,000,000
Dr. Guo Hongwei	Beijing Shengnuoji	363,636	3,000,000

Upon the completion of the above-mentioned equity transfer in 2020, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Dr. Zhou Hongfeng, Long Star Growth, Shidai Weiye, Guangrui Hongxiang, Dr. Zhou Pengfei, Zhongheng Tongde and Dr. Guo Hongwei as to approximately 39.56%, 15.75%, 11.67%, 7.87%, 6.11%, 5.89%, 5.56%, 4.77%, 2.57% and 0.26%, respectively.

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Series B Financing

Pursuant to the capital contribution agreement dated December 24, 2020 entered into among the series B financing investors set forth below, our Company and our then Shareholders, the registered capital of the Company was increased from RMB141,428,600 to RMB157,334,601, and the following series B financing investors agreed to subscribe the increased registered capital of the Company in a total amount of RMB15,906,001 at an aggregate consideration of RMB168,700,000 (the “**Series B Financing**”). The respective subscription amount in the registered capital of the Company and consideration paid by the subscribers in the Series B Financing were set out as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration (RMB)
Nanning Huiyou Xingyao Equity Investment Fund Partnership (Limited Partnership) (南寧匯友興曜股權投資基金合夥企業(有限合夥)) (“ Huiyou Xingyao ”)	9,966,002	105,700,000
Nanjing BGI Co-win Fund I Venture Capital Enterprise (Limited Partnership) (南京華大共贏一號創業投資企業(有限合夥)) (“ BGI Co-win Fund I ”)	1,885,714	20,000,000
Hainan Weifeng Network Technology Partnership (Limited Partnership) (海南偉豐網絡科技合夥企業(有限合夥)) (“ Hainan Weifeng ”)	1,885,714	20,000,000
Hangzhou Sanhua Hongdao Venture Capital Partnership (Limited Partnership) (杭州三花弘道創業投資合夥企業(有限合夥)) (“ Sanhua Hongdao ”)	1,225,714	13,000,000
Shaoshan Jinyu Industry and Trade Co., Ltd (韶山金羽工貿有限公司) (“ Shaoshan Jinyu ”) ⁽¹⁾	942,857	10,000,000
Total	15,906,001	168,700,000

(1) Pursuant to the equity transfer agreement dated May 20, 2021 entered into between Shaoshan Jinyu and Shaoshan Hongyu Technology Co., Ltd (韶山鴻宇科技有限公司) (“**Shaoshan Hongyu**”), for its internal restructuring purpose, Shaoshan Hongyu agreed to acquire the registered capital of the Company in a total amount of RMB942,857 at an aggregate consideration of RMB10,000,000 from Shaoshan Jinyu, reflecting previous contributions made by Shaoshan Jinyu in the Company.

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Upon completion of the Series B Financing, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Dr. Zhou Hongfeng, Huiyou Xingyao, Long Star Growth, Hainan Boyou, Guangrui Hongxiang, Dr. Zhou Pengfei, Zhongheng Tongde, BGI Co-win Fund I, Hainan Weifeng, Sanhua Hongdao, Shaoshan Jinyu and Dr. Guo Hongwei as to approximately 35.56%, 14.16%, 10.49%, 7.08%, 6.33%, 5.49%, 5.29%, 4.99%, 4.29%, 2.31%, 1.20%, 1.20%, 0.78%, 0.60% and 0.23%.

Series B+ Financing

Pursuant to the capital contribution agreements dated January 28, 2021 entered into among the series B+ financing investors set forth below, our Company and our then Shareholders, the registered capital of the Company was increased from RMB157,334,601 to RMB159,220,315, and the following series B+ financing investors agreed to subscribe the increased registered capital of the Company in a total amount of RMB1,885,714 at an aggregate consideration of RMB20,000,000 (the “**Series B+ Financing**”). The respective subscription amount in the registered capital of the Company and consideration paid by the subscribers in the Series B+ Financing were set out as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration (RMB)
Zhuhai Shengyi Investment Partnership (Limited Partnership) (珠海盛溢投資合夥企業(有限合夥)) (“ Zhuhai Shengyi ”)	942,857	10,000,000
Wuhan Baiying Huizhi Venture Capital Fund Partnership (Limited Partnership) (武漢百贏匯智創業投資基金合夥企業(有限合夥)) (“ Baiying Huizhi ”)	942,857	10,000,000
Total	1,885,714	20,000,000

Upon the completion of the Series B+ Financing, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Dr. Zhou Hongfeng, Huiyou Xingyao, Long Star Growth, Hainan Boyou, Guangrui Hongxiang, Dr. Zhou Pengfei, Zhongheng Tongde, BGI Co-win Fund I, Hainan Weifeng, Sanhua Hongdao, Shaoshan Hongyu, Zhuhai Shengyi, Baiying Huizhi and Dr. Guo Hongwei as to approximately 35.14%, 13.99%, 10.36%, 6.99%, 6.26%, 5.43%, 5.23%, 4.93%, 4.24%, 2.28%, 1.18%, 1.18%, 0.77%, 0.59%, 0.59%, 0.59% and 0.23%, respectively.

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Series B++ Financing

Pursuant to the capital contribution agreements dated June 18, 2021, August 9, 2021 and August 17, 2021 entered into among the series B++ financing investors set forth below, our Company and our then Shareholders, the registered capital of the Company was increased from RMB159,220,315 to RMB165,071,660, and the following series B++ financing investors agreed to subscribe the increased registered capital of the Company in a total amount of RMB5,851,345 at an aggregate consideration of RMB73,500,000 (the “**Series B++ Financing**”). The respective subscription amount in the registered capital of the Company and consideration paid by the subscribers in the Series B++ Financing were set out as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration (RMB)
Gongqingcheng Huiyou Xingyao Phase II Equity Investment Partnership (Limited Partnership) (共青城匯友興曜二期股權投資合夥企業(有限合夥)) (“ Gongqingcheng Huiyou ”)	2,985,380	37,500,000
Guangdong Xingyao No.4 Equity Investment Partnership (Limited Partnership) (廣東星耀四號股權投資合夥企業(有限合夥)) (“ Guangdong Xingyao ”)	1,592,203	20,000,000
Suqian Qianshan Xinrong Venture Capital Partnership (Limited Partnership) (宿遷千山信榮創業投資合夥企業(有限合夥)) (“ Qianshan Xinrong ”)	1,273,762	16,000,000
Total	5,851,345	73,500,000

Upon the completion of the Series B++ Financing, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Dr. Zhou Hongfeng, Huiyou Xingyao, Long Star Growth, Hainan Boyou, Guangrui Hongxiang, Dr. Zhou Pengfei, Zhongheng Tongde, Gongqingcheng Huiyou, BGI Co-win Fund I, Hainan Weifeng, Guangdong Xingyao, Qianshan Xinrong, Sanhua Hongdao, Shaoshan Hongyu, Zhuhai Shengyi, Baiying Huizhi and Dr. Guo Hongwei as to approximately 33.89%, 13.49%, 10.00%, 6.75%, 6.04%, 5.24%, 5.05%, 4.76%, 4.09%, 2.20%, 1.81%, 1.14%, 1.14%, 0.96%, 0.77%, 0.74%, 0.57%, 0.57%, 0.57% and 0.22%, respectively.

Equity Transfer in September 2021

On September 16, 2021, CSPC-NBP, Yuan Qian, Dr. Zhou Hongfeng, Long Star Growth, Hainan Boyou and Guangrui Hongxiang transferred the equity interests they held in the Company, representing approximately 3.39%, 1.35%, 0.67%, 0.52%, 0.50% and 0.48% of the total registered capital of the Company, respectively, to Caizhi No.2, a limited partnership established on August 27, 2021, as an employee incentive platform of the Company, in exchange for the partnership interests in Caizhi No.2, representing approximately 24.49%, 9.75%, 4.87%, 3.78%, 3.65% and 3.44% of the partnership interest of Caizhi No.2, respectively. For more details on the employee incentive platforms of the Company, please refer to the paragraphs headed “– Employee Incentive Platforms” in this section.

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Upon the completion of the equity transfer in September 2021, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Caizhi No.2, Dr. Zhou Hongfeng, Huiyou Xingyao, Long Star Growth, Hainan Boyou, Guangrui Hongxiang, Dr. Zhou Pengfei, Zhongheng Tongde, Gongqingcheng Huiyou, BGI Co-win Fund I, Hainan Weifeng, Guangdong Xingyao, Qianshan Xinrong, Sanhua Hongdao, Shaoshan Hongyu, Zhuhai Shengyi, Baiying Huizhi and Dr. Guo Hongwei as to approximately 30.50%, 12.14%, 10.00%, 6.92%, 6.07%, 6.04%, 4.71%, 4.54%, 4.28%, 4.09%, 2.20%, 1.81%, 1.14%, 1.14%, 0.96%, 0.77%, 0.74%, 0.57%, 0.57%, 0.57% and 0.22%, respectively.

Conversion into a Joint Stock Company

On January 13, 2022, the Company was converted into a joint stock company with its corporate name changed to Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司). Upon the completion of the conversion, the registered capital of the Company became RMB168,000,000 divided into 168,000,000 Shares with a nominal value of RMB1.00 each.

Series C Financing

Pursuant to the capital contribution agreement dated July 15, 2022 entered into among the series C financing investors set forth below, our Company and our then Shareholders (the “**Series C Financing Agreement**”), the registered capital of the Company was increased from RMB168,000,000 to RMB182,000,000, and the following series C financing investors agreed to subscribe the increased registered capital of the Company in a total amount of RMB14,000,000 at an aggregate consideration of RMB200,000,000 (the “**Series C Financing**”). The respective subscription amount in the registered capital of the Company and consideration paid by the subscribers in the Series C Financing were set out as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration (RMB)
Wuhan Optics Valley New Technology Industry Investment Co., Ltd (武漢光穀新技術產業投資有限公司) (“ Guanggu New Technology ”)	7,000,000	100,000,000
Wuhan Optics Valley Health Industry Investment Ltd. (武漢光穀健康產業投資有限公司) (“ Guanggu Health ”)	5,600,000	80,000,000
Wuhan Optics Valley Growth Venture Capital Fund Co., Ltd (武漢光穀成長創業投資基金有限公司) (“ Guanggu Growth ”)	1,400,000	20,000,000
Total	14,000,000	200,000,000

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of the Series C Financing, the Company was owned by CSPC-NBP, Yuan Qian, Wuhan Caizhi, Caizhi No.2, Dr. Zhou Hongfeng, Huiyou Xingyao, Long Star Growth, Hainan Boyou, Guangrui Hongxiang, Guanggu New Technology, Dr. Zhou Pengfei, Guanggu Health, Zhongheng Tongde, Gongqingcheng Huiyou, BGI Co-win Fund I, Hainan Weifeng, Guangdong Xingyao, Guanggu Growth, Qianshan Xinrong, Sanhua Hongdao, Shaoshan Hongyu, Zhuhai Shengyi, Baiying Huizhi and Dr. Guo Hongwei as to approximately 28.15%, 11.21%, 9.23%, 6.38%, 5.60%, 5.57%, 4.35%, 4.19%, 3.95%, 3.85%, 3.77%, 3.08%, 2.03%, 1.67%, 1.05%, 1.05%, 0.89%, 0.77%, 0.71%, 0.69%, 0.53%, 0.53%, 0.53% and 0.20%, respectively.

CONCERT PARTY ARRANGEMENT

In order to fulfill the vision of discovering and developing innovative drugs for healthier lives of patients, the Founders decided to establish a biotechnology company that is dedicated to developing BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. For more details of the background and circumstances leading to the formation of the Group, please refer to the paragraphs headed “– Establishment and Corporate Development – Establishment and Major Shareholding Changes in the Company Prior to 2016” in this section. To reduce the impact of dilution on ownership and to exercise effective control over the operations and corporate matters of the Company, the AIC Parties decided to enter into a concert party agreement. Pursuant to a concert party agreement dated June 30, 2018 (the “**Concert Party Agreement**”) and supplemental concert party agreements dated October 26, 2020 and June 2, 2023, entered into by Yuan Qian, Dr. Zhou Hongfeng, Dr. Zhou Pengfei and Wuhan Caizhi, the AIC Parties agreed (i) to act in concert by way of reaching consensus on proposals related to the Group’s daily management and operation presented to all general meetings and Board meetings of the Company; and (ii) that when no consensus can be reached, the AIC Parties shall vote in concurrence with Yuan Qian on the proposals, or, in the event of Yuan Qian’s absence from voting, the AIC Parties shall vote in concurrence with the AIC Party with the highest shareholding percentage among the AIC Parties who votes at the meetings. Pursuant to the aforesaid supplemental agreement dated June 2, 2023, the Concert Party Agreement shall be effective from the date of execution until it is terminated by written agreement of all AIC Parties. As of the Latest Practicable Date, the AIC Parties were in aggregate entitled to exercise approximately 29.81% of the voting rights in the Company. Upon completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), the AIC Parties will hold approximately [REDACTED]% of our total [REDACTED] share capital. The AIC Parties have no specific plan to release the concert party relationship. Therefore, the AIC Parties expect that they will be able to maintain effectively control over the operations and corporate matters of the Company thereafter.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

EMPLOYEE INCENTIVE PLATFORMS

In recognition of the contributions of our employees and to incentivize them to further promote our development, Wuhan Caizhi and Caizhi No.2 were established in the PRC as our employee incentive platforms.

Wuhan Caizhi

Wuhan Caizhi is a limited partnership established in the PRC on September 21, 2015 and managed by its executive partner, Yuan Qian. As the executive partner of Wuhan Caizhi, Yuan Qian is able to determine the daily operations of Wuhan Caizhi, while the voting rights held by Wuhan Caizhi in the Company shall be exercised pursuant to the Concert Party Agreement. For more details, please refer to the paragraphs headed “– Concert Party Arrangement” in this section. As of the Latest Practicable Date, Wuhan Caizhi had 25 limited partners and directly held approximately 9.23% equity interests in the Company. Its partners are set out as follows:

Partners	Current position(s) in the Company	Partnership interest
Nanjing Huiyou Jucai Enterprise Management Partnership (Limited Partnership) (南京匯友聚才企業管理合夥企業(有限合夥) (“ Huiyou Jucai ”))	N/A	50.76%
Nanjing Huiyou Juzhi Enterprise Management Partnership (Limited Partnership) (南京匯友聚智企業管理合夥企業(有限合夥) (“ Huiyou Juzhi ”))	N/A	29.33%
Dr. Zhou Pengfei	Co-founder of the Group, chairman of the Board, executive Director, chief executive officer	8.28%
Dr. Yi Jizu	Senior vice president of quality	3.55%
Zhang Jing	Supervisor, senior director of the R&D center	0.53%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Partners	Current position(s) in the Company	Partnership interest
Yuan Qian	Co-founder of the Group, non-executive Director	0.36%
Dr. Zhou Hongfeng	Co-founder of the Group, non-executive Director	0.18%
Other key employees ⁽¹⁾	N/A	7.01%
Total		100.00%

(1) As of the Latest Practicable Date, other key employees as limited partners of Wuhan Caizhi and their respective partnership interest were approximately: Qiu Jianping (3.95%), Xiong Hui (0.47%), Li Gang (0.39%), Hu Jianzhong (0.38%), Li Si (0.28%), Yu Dunyang (0.19%), Yan Yongxiang (0.19%), Fang Lijuan (0.16%), Liu Yang (0.14%), Xiao Ying (0.14%), Shao Mingsheng (0.14%), Ding Mingjian (0.11%), Wu Shujuan (0.07%), Yang Jinxia (0.07%), Kuang Shenmei (0.07%), Yao Lan (0.07%), Wang Rui (0.06%), Zhang Qiang (0.06%), Ku Ying (0.05%) and Li Bo (0.02%), respectively. As of the Latest Practicable Date, all of them were current or former employees of the Company.

As of the Latest Practicable Date, Li Si served as an executive director of Shijiazhuang Shiyou and Nanjing Youbodi, and Xiao Ying served as a supervisor of Shijiazhuang Shiyou and Nanjing Youbodi. As such, Li Si and Xiao Ying were connected persons of the Company. Save as disclosed above, as of the Latest Practicable Date, each of limited partners categorized as “other key employees” was an independent third party of the Company.

Huiyou Jucai is a limited partnership established in the PRC on August 26, 2021 and managed by its general partner, Dr. Zhou Pengfei. As of the Latest Practicable Date, Huiyou Jucai had 12 limited partners. Its partners are set out as follows:

Partners	Current position(s) in the Company	Partnership interest
Dr. Zhou Pengfei	Co-founder of the Group, chairman of the Board, executive Director, chief executive officer	49.95%
Dr. Yi Jizu	Supervisor, senior vice president of quality	12.71%
Zhang Jing	Supervisor, senior director of the R&D center	10.90%
Other key employees ⁽¹⁾	N/A	26.45%
Total		100.00%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (1) As of the Latest Practicable Date, other key employees as limited partners of Huiyou Jucai and their respective partnership interest were approximately: Xiong Hui (4.57%), Li Si (4.24%), Fang Lijuan (3.99%), Yao Lan (2.84%), Xiao Ying (2.26%), Kuang Shenmei (2.24%), Shao Mingsheng (2.02%), Yan Yongxiang (2.01%), Ku Ying (1.70%) and Li Bo (0.57%), respectively. As of the Latest Practicable Date, all of them were current or former employees of the Company.

As of the Latest Practicable Date, Li Si served as an executive director of Shijiazhuang Shiyu and Nanjing Youbodi, and Xiao Ying served as a supervisor of Shijiazhuang Shiyu and Nanjing Youbodi. As such, Li Si and Xiao Ying were connected persons of the Company. Save as disclosed above, as of the Latest Practicable Date, each of limited partners categorized as “other key employees” was an independent third party of the Company.

Huiyou Juzhi is a limited partnership established in the PRC on August 27, 2021 and managed by its general partner, Dr. Zhou Pengfei. As of the Latest Practicable Date, Huiyou Juzhi had 38 limited partners. Its partners are set out as follows:

Partners	Current position(s) in the Company	Partnership interest
Dr. Zhou Pengfei	Co-founder of the Group, chairman of the Board, executive Director, and chief executive officer	10.33%
Dr. Huang Shaoyi	Senior director of the clinical department	10.33%
Dr. Yang Bin	Vice president of the manufacturing center	4.13%
Other key employees ⁽¹⁾	N/A	75.21%
Total		100.00%

- (1) As of the Latest Practicable Date, other key employees as limited partners of Huiyou Juzhi and their respective partnership interest were approximately: Shi Jian (6.20%), Liu Tingting (4.13%), Li Xiaoqing (4.13%), Luo Fengyan (4.13%), Zhang Ying (4.13%), Wang Xiong (4.13%), Li Mingxin (3.10%), Gong Cheng (3.10%), Zeng Liang (3.10%), Cong Wenjuan (3.10%), Luo Jin (3.10%), Wan Bo (3.10%), Lei Yang (2.07%), Shen Li (2.07%), Tan Qinggang (2.07%), Yi Li (2.07%), Yin Zhicheng (2.07%), Zheng Jianhua (2.07%), Liu Jiayan (1.65%), Hua Shan (1.45%), Xue Rong (1.04%), Liu Xiaoyan (1.04%), Luo Weina (1.04%), Wang Xin (1.03%), Luo Fang (1.03%), Ni Qian (1.03%), Xu Shasha (1.03%), Xue Yan (1.03%), Yin Haibing (1.03%), Pei Mengwan (1.03%), Zhang Huanhuan (1.03%), Miao Shundong (1.03%), Xie Siwu (0.62%), Peng Chu (0.41%), Xiao Mengyi (0.41%) and Jiang Xiangjun (0.41%), respectively. As of the Latest Practicable Date, all of them were current or former employees of the Company.

As of the Latest Practicable Date, Shi Jian served as a supervisor of Wuhan Youwei, and therefore was a connected person of the Company. Save as disclosed above, as of the Latest Practicable Date, each of limited partners categorized as “other key employees” was an independent third party of the Company.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Caizhi No.2

Caizhi No.2 is a limited partnership established in the PRC on August 27, 2021. The general partner of Caizhi No.2 is Wuhan Huiyou Juyou Enterprise Management Co., Ltd (武漢匯友聚友企業管理有限公司), which was in turn owned as to 90% by Dr. Zhou Pengfei and as to 10% by Zhang Jing (being a Supervisor), as of the Latest Practicable Date. Pursuant to the partnership agreement of Caizhi No.2, its general partner will exercise its voting power in the Company following the instruction of the management committee of Caizhi No.2, which consists of 11 members. The 11 members of the management committee of Caizhi No.2 consists of six members nominated by CSPC-NBP, Guangrui Hongxiang, Hainan Boyou, Long Star Growth, Yuan Qian and Dr. Zhou Hongfeng (being the shareholders who transferred the equity interests they held in the Company to Caizhi No.2 for its establishment), respectively, and five members nominated by the management team of the Company. All decisions made by the management committee of Caizhi No.2 shall be approved by the majority of all members. As of the Latest Practicable Date, Caizhi No.2 had 21 limited partners and directly held approximately 6.38% equity interest in the Company. Its partners are set out as follows:

Partners	Current position(s) in the Company	Partnership interest
CSPC-NBP ⁽¹⁾	N/A	24.49%
Dr. Zhou Pengfei	Co-founder of the Group, chairman of the Board, executive Director, and chief executive officer	23.71%
Yuan Qian ⁽¹⁾	Co-founder of the Group and non-executive Director	9.75%
Dr. Yi Jizu	Supervisor, senior vice president of quality	5.03%
Dr. Zhou Hongfeng ⁽¹⁾	Co-founder of the Group, non-executive Director	4.87%
Zhang Jing	Supervisor, senior director of the R&D center	3.94%
Long Star Growth ⁽¹⁾	N/A	3.78%
Hainan Boyou ⁽¹⁾	N/A	3.65%
Guangrui Hongxiang ⁽¹⁾	N/A	3.44%
Dr. Yang Bin	Vice president of the manufacturing center	2.63%
Dr. Huang Shaoyi	Senior director of the clinical department	0.44%
Wuhan Huiyou Juyou Enterprise Management Co., Ltd (武漢匯友聚友企業管理有限公司)	N/A	0.04%
Other key employees ⁽²⁾	N/A	14.23%
Total		100.00%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (1) *On September 16, 2021, CSPC-NBP, Yuan Qian, Dr. Zhou Hongfeng, Long Star Growth, Hainan Boyou and Guangrui Hongxiang transferred the equity interests they held in the Company, representing approximately 3.39%, 1.35%, 0.67%, 0.52%, 0.50% and 0.48% of the total registered capital of the Company, respectively, to Caizhi No.2, a limited partnership established on August 27, 2021, as an employee incentive platform of the Company, in exchange for the partnership interests in Caizhi No.2, representing approximately 24.49%, 9.75%, 4.87%, 3.78%, 3.65% and 3.44%, respectively.*
- (2) *As of the Latest Practicable Date, other key employees as limited partners of Caizhi No.2 and their respective partnership interest were approximately: Wen Zhicheng (4.38%), Li Si (3.50%), Xiong Hui (2.19%), Fang Lijuan (1.31%), Shi Jian (0.65%), Yan Yongxiang (0.44%), Yang Rui (0.44%), Shao Mingsheng (0.44%), Kuang Shenmei (0.44%) and Xiao Ying (0.44%), respectively. As of the Latest Practicable Date, all of them were current or former employees of the Company.*

As of the Latest Practicable Date, Shi Jian served as a supervisor of Wuhan Youwei; Li Si served as an executive director of Shijiazhuang Shiyou and Nanjing Youbodi; and Xiao Ying served as a supervisor of Shijiazhuang Shiyou and Nanjing Youbodi. As such, Shi Jian, Li Si and Xiao Ying were connected persons of the Company. Save as disclosed above, as of the Latest Practicable Date, each of limited partners categorized as “other key employees” was an independent third party of the Company.

MAJOR ACQUISITIONS, DISPOSALS AND MERGERS

During the Track Record Period and up to the Latest Practicable Date, we did not conduct any acquisitions, disposals and mergers that we consider to be material to us.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED] INVESTMENTS

Summary of [REDACTED] Investments

The following table sets forth a summary of the details of the [REDACTED] Investments:

	Series Pre-A Financing ⁽¹⁾	Series A Financing	Equity Transfer in 2020	Series B Financing	Series B+ Financing	Series B++ Financing	Series C Financing
Amount of registered capital subscribed for	RMB10,000,000	RMB31,428,600	/	RMB15,906,001	RMB1,885,714	RMB5,851,345	RMB14,000,000
Amount of registered capital transferred	/	RMB49,342,800	RMB4,000,000	/	/	/	/
Amount of consideration paid for the subscription of registered capital	RMB50,000,000	RMB157,200,000 ⁽²⁾	/	RMB168,700,000	RMB20,000,000	RMB73,500,000	RMB200,000,000
Amount of consideration paid for the transfer of registered capital	/	RMB246,804,000	RMB33,000,000	/	/	/	/
Post-money valuation of the Company	RMB550,000,000	RMB900,000,000 ⁽³⁾	RMB1,166,790,000	RMB1,668,700,000 ⁽⁴⁾	RMB1,688,700,000 ⁽⁵⁾	RMB2,073,500,000 ⁽⁶⁾	RMB2,600,000,000 ⁽⁷⁾
Date of agreement(s)	February 2, 2016	January 9, 2018 January 10, 2018 March 22, 2018 April 27, 2018 ⁽²⁾	August 17, 2020	December 24, 2020	January 28, 2021	June 18, 2021 August 9, 2021 August 17, 2021 August 19, 2021	July 15, 2022
Date of payment of full consideration	August 11, 2016		August 28, 2020	August 19, 2021	March 29, 2021		October 12, 2022
Cost per Share paid under the [REDACTED] Investment	RMB5.00	RMB5.00	RMB8.25	RMB10.61	RMB10.61	RMB12.56	RMB14.29
[REDACTED] to the [REDACTED] ⁽⁸⁾	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Series Pre-A Financing ⁽¹⁾	Series A Financing	Equity Transfer in 2020	Series B Financing	Series B+ Financing	Series B++ Financing	Series C Financing
Basis of consideration	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the then development of the Company's drug candidates and technology platform.	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the Company's post-money valuation after the completion of the Series Pre-A Financing and the then development of the Company's drug candidates and technology platform.	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the Company's post-money valuation after the completion of the Series A Financing and the then development of the Company's drug candidates and technology platform.	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the Company's post-money valuation after the completion of the Series A Financing and the then development of the Company's drug candidates and technology platform.	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the Company's post-money valuation after the completion of the Series B Financing.	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the Company's post-money valuation after the completion of the Series B+ Financing and the then development of the Company's drug candidates.	The consideration was determined based on arm's length negotiations among the relevant parties taking into account the Company's post-money valuation after the completion of the Series B++ Financing and the then development of the Company's drug candidates.
Use of proceeds and whether they have been fully utilized	We utilized the proceeds for clinical promotion of core product pipelines, research and development of preclinical product pipelines and the payment of our daily operation and management fees, etc. As of the Latest Practicable Date, we had fully utilized the proceeds from the Series Pre-A Financing, Series A Financing, Series B Financing, Series B+ Financing and Series B++ Financing, and had utilized approximately 50% of the proceeds from the Series C Financing. The remaining proceeds from the Series C Financing are expected to be used to repay a portion of our bank loan in several installments, with the final installment due in July 2023, and support the development of our drug candidates.						
Lock-up	Pursuant to the applicable PRC laws and regulations, within the 12 months following the [REDACTED], no current Shareholders (including the [REDACTED] Investors) may dispose of any of the Shares held by them.						
Strategic benefits	At the time of the [REDACTED] Investments, the Directors were of the view that (i) the Company would benefit from the additional capital provided by the [REDACTED] Investors and their market influence, knowledge and experience and (ii) the [REDACTED] Investments demonstrated the [REDACTED] Investors' confidence in the operation and development of our Group.						

(1) The equity interests held by the Series Pre-A Financing investors were all subsequently transferred to other Shareholders. For More details, please refer to the paragraphs headed “– Establishment and Corporate Development” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (2) Pursuant to the Supplemental Agreement, CSPC-NBP, Shidai Weive and Guangrui Hongxiang agreed to further contribute a total of RMB42,800,000 in addition to the consideration payable by them in the Series A Financing (i.e. RMB157,200,000) as contingent consideration for the Company to complete certain milestones as set forth in the Supplemental Agreement. As of March 26, 2021, the Additional Consideration was all settled.
- (3) The increase in the valuation of the Company from the Series Pre-A Financing was primarily due to (i) the significant progress made in the establishment of our proprietary YBODY[®] platform; and (ii) the successful development of the drug candidates, including obtaining clinical trials approvals for M802 in September 2017 and M701 in February 2018, respectively, and introducing new drug candidates.
- (4) The increase in the valuation of the Company from the Series A Financing to the Series B Financing was primarily due to (i) the significant progress made in the establishment of our proprietary platforms, including the establishment of the Check-BODY platform and Nano-YBODY[™] platform in 2018, which enable us to quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways, as well as filing the PCT patent application for the protection of our Check-BODY platform in July 2019; (ii) the successful development of the drug candidates, including (a) the development of M802; receiving the patents issued for the protection of M802 in China and YBODY[®] platform in CD3 and HER2 targets in U.S. in December 2018, continuing on the Phase I clinical trial in China demonstrating favorable safety profile and obtaining FDA IND approvals for the clinical investigation in U.S. in August 2019; (b) the development of M701; commencing the Phase I clinical trial in China in January 2019, obtaining FDA IND approvals for the clinical investigation in U.S. in October 2019, and receiving satisfactory interim results from the clinical data of Phase I clinical trial in December 2020; and (c) the development of other drug candidates; obtaining FDA IND approval for our clinical investigation of Y150 in U.S. in August 2020.
- (5) The increase in the valuation of the Company from the Series B Financing to the Series B+ Financing was due to the proceeds received from the Series B+ Financing.
- (6) The increase in the valuation of the Company from the Series B++ Financing to the Series B+++ Financing was primarily due to (i) the successful development of the drug candidates, including (a) the development of M802; completing the Phase I clinical trial in China, demonstrating favorable safety profile; (b) the development of M701; obtaining approval from the ethic committee for Phase II clinical trial in June 2021 and initiating the Phase II clinical trial in China; (c) the development of Y150; obtaining IND approval from the ethic committee for Phase I clinical trial in April 2021 and initiating the Phase I clinical trial in China; (d) the development of Y101D; obtaining NMPA IND approval for the clinical investigation in metastatic or locally advanced solid tumors in China in May 2021; (e) the development of Y400; commencing preclinical studies and receiving satisfactory animal studies results regarding efficacy and safety; and (f) the development of other drug candidates; initiating preclinical studies of other drug candidates, such as Y332; and (ii) optimizing corporate governance and management structure, including establishing reasonable governance structure, maintaining compliance and standardized daily operation.
- (7) The increase in the valuation of the Company from the Series B+++ Financing to the Series C Financing was primarily due to (i) the successful development of the drug candidates, including commencing the Phase I clinical trial of Y101D for the treatment of metastatic or locally advanced solid tumors in China in August 2021, initiating clinical research of Y150 in August 2021, completing the Phase Ia clinical trial of Y2019 in China in August 2022 with satisfactory 7-day and 90-day safety data post immunization, and receiving good R&D test results of Y332; and (ii) achieving product commercialization by establishing business cooperation with CMS Vision in relation to Y400 in July 2022.
- (8) The [REDACTED] to the [REDACTED] is calculated based on the currency translation of HK\$1 to RMB[REDACTED] and on the basis of the [REDACTED] of HK\$[REDACTED], the mid-point of the proposed range of the [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Valuation of Our Company

Based on the [REDACTED] of HK\$[REDACTED] (the mid-point of the indicative [REDACTED] range) and assuming the [REDACTED] is not exercised, the valuation of the Company upon [REDACTED] will be approximately HK\$[REDACTED] (the “**Proposed [REDACTED] Valuation**”).

The increase in the post-money valuation of the Company from the Series C Financing to the Proposed [REDACTED] Valuation mainly reflects the progress of the Company’s pipeline candidates, including but not limited to (i) the development of M701: currently enrolling patients of the Phase II clinical trial evaluating the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA (M701 is currently well tolerated in the treatment arm) and commencing a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022; (ii) the development of Y101D: obtaining the ethic committee and IND approvals for a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of pancreatic cancer in November and December 2022, respectively, obtaining IND approval for a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of hepatocellular carcinoma (HCC) and other advanced solid tumors in December 2022, commencing a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China in February 2023, and commencing a Phase Ib/II clinical trial in March 2023; (iii) the development of Y400: receiving IND approval in China in April 2023; and (iv) the development of Y332: receiving IND approval in China in April 2023. The continuous progress of our business development is expected to support the step-up in the proposed [REDACTED] valuation of the Group.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Capitalization of the Company

The following table is a summary of the capitalization of the Company:

Shareholder	As at the Latest Practicable Date		Immediately Following the Completion of the [REDACTED] and Conversion of the [REDACTED] Shares into H Shares (Assuming the [REDACTED] is not Exercised)					
	[REDACTED] Shares ⁽³⁾		H Shares ⁽³⁾		[REDACTED] Shares ⁽³⁾		Total Shares	
	Percentage of Shareholding in the		Percentage of Shareholding in the H		Percentage of Shareholding in the		Percentage of Shareholding in the Total	
	Number of Shares	[REDACTED] Shares	Number of Shares	in the H Shares	Number of Shares	[REDACTED] Shares	Number of Shares	Issued Share Capital
CSPC-NBP	51,241,785	28.15%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Yuan Qian ⁽²⁾	20,399,933	11.21%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Wuhan Caizhi ⁽²⁾	16,792,707	9.23%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Caizhi No. 2 ⁽²⁾	11,620,411	6.38%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Zhou Hongfeng ⁽²⁾	10,199,921	5.60%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Huiyou Xingyao ⁽²⁾	10,142,797	5.57%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Long Star Growth	7,916,510 ⁽¹⁾	4.35%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Hainan Boyou	7,628,713	4.19%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Guangrui Hongxiang	7,196,835	3.95%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Guanggu New Technology ⁽²⁾	7,000,000	3.85%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Zhou Pengfei ⁽²⁾	6,869,744 ⁽¹⁾	3.77%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Guanggu Health ⁽²⁾	5,600,000	3.08%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Zhongheng Tongde	3,700,872	2.03%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Gongqingcheng Huiyou ⁽²⁾	3,038,340	1.67%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
BGI Co-win Fund I ⁽²⁾	1,919,166	1.05%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Hainan Weifeng	1,919,166	1.05%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Guangdong Xingyao	1,620,448	0.89%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Guanggu Growth ⁽²⁾	1,400,000	0.77%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Qianshan Xinrong	1,296,358	0.71%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Sanhua Hongdao	1,247,458	0.69%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Shaoshan Hongyu	959,583	0.53%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Baiying Huizhi	959,583	0.53%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Zhuhai Shengyi ⁽²⁾	959,583	0.53%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Guo Hongwei ⁽²⁾	370,087	0.20%	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Public Shareholders participated in the [REDACTED]	–	–	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total	182,000,000	100%	[REDACTED]	100%	[REDACTED]	100%	[REDACTED]	100%

(1) These Shares are [REDACTED] Foreign Shares.

(2) Based on these Shareholders’ own business considerations, they decided not to convert all or part of [REDACTED] Shares held by them into H Shares in parallel with the [REDACTED].

(3) For the avoidance of doubt, both [REDACTED] Shares and H Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Rights of the [REDACTED] Investors

The [REDACTED] Investors were granted certain special rights, including but not limited to anti-dilution right, redemption right, information right, director/supervisor nomination right and senior management appointment right.

Pursuant to the special rights termination agreements entered into between the Company and each of the [REDACTED] Investors (other than the Series C Financing investors) dated October 20, 2021, and the Series C Financing Agreement, no special rights of the [REDACTED] Investors will exist after the [REDACTED].

Information about our [REDACTED] Investors

Our [REDACTED] Investors include Sophisticated Investors, such as CSPC-NBP, a major pharmaceutical company, who has made meaningful investment in the Company at least six months before the [REDACTED]. The background information on our [REDACTED] Investors are as set out below.

CSPC-NBP

CSPC-NBP is a limited liability company established in the PRC on April 23, 2003, which was owned directly as to approximately 54.06% by CSPC and indirectly as to approximately 45.94% by CSPC through its wholly-owned entity as of the Latest Practicable Date. CSPC is a company listed on the Stock Exchange (Stock code: 1093.HK) mainly engaged in manufacture and sale of pharmaceutical products and is a leading pharmaceutical group in China with strong innovation, R&D and marketing capabilities, as well as extensive investment experience in the healthcare industry. CSPC-NBP, as a Sophisticated Investor, is a modern pharmaceutical enterprise mainly producing innovative drugs and has developed class 1 new chemical drug with independent intellectual property rights for the treatment of acute ischemic stroke in China. As of the Latest Practicable Date, based on the public information, CSPC-NBP had invested in approximately 20 companies, including pharmaceutical companies and other companies in the healthcare industry. CSPC-NBP had also served as a limited partner in approximately ten investment funds, as of the Latest Practicable Date.

To the best knowledge of the Directors, save as disclosed above, each of CSPC-NBP's ultimate beneficial owners is an independent third party, and, together with CSPC-NBP, have no relationship with any connected persons of the Company or other [REDACTED] Investors.

Guangrui Hongxiang

Guangrui Hongxiang is a limited partnership established in the PRC on August 5, 2016 and its general partner is Guoxin Sichuang, which was in turn owned as to 60% by Wang Hongjie (王宏傑) as of the Latest Practicable Date. As of the Latest Practicable Date, Guangrui Hongxiang had 14 limited partners, the largest of which was Beijing Zhonglian Tonghui Investment Holdings Co., Ltd (北京中聯通匯投資控股有限公司) holding approximately 21.29% of its partnership interest, which was in turn owned as to 90% by Li Yunxia (李運霞). Guangrui Hongxiang is an investment arm of Guoxin Sichuang which is mainly engaged in equity investment and assets management. As of the Latest Practicable Date, as confirmed by Guangrui Hongxiang, the total assets managed by Guoxin Sichuang was approximately RMB2 billion.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

To the best knowledge of the Directors, save as disclosed above, each of Guangrui Hongxiang, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Long Star Growth

Long Star Growth was incorporated in Hong Kong on January 14, 2014 and an indirect wholly-owned subsidiary of CDH Growth Fund III (USD Parallel), L.P. (“**CDH Growth Fund**”) as of the Latest Practicable Date. As of the Latest Practicable Date, the general partner of CDH Growth Fund was CDH R-III Parallel Holdings Company Limited, which was in turn controlled by CDH Griffin Holdings Company Limited (“**CDH Griffin**”) through its controlled entities. As of the Latest Practicable Date, CDH Griffin was indirectly owned as to 33.2% by Wu Shangzhi, the single largest shareholder of CDH Griffin. As of the Latest Practicable Date, CDH Growth Fund had 20 limited partners, the largest of which was Prowell Ventures Pte Ltd, holding approximately 29.24% of its partnership interest, which was a limited company established by the government of Singapore. Long Star Growth is engaged in investments in the medical, healthcare and related industries.

To the best knowledge of the Directors, save as disclosed above, each of Long Star Growth and its ultimate beneficial owners is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Tongde Qianyuan

Three funds managed by their respective general partners which were all in turn managed by Tongde Qianyuan (Beijing) Investment Management Co., Ltd (同德乾元(北京)投資管理有限公司) (“**Tongde Qianyuan**”) made [REDACTED] Investments in the Company. As of the Latest Practicable Date, Tongde Qianyuan was owned as to approximately 72.38% by Wen Zhicheng (former secretary to the Board). Details of these three funds are set out as below:

(i) Zhongheng Tongde

Zhongheng Tongde is a limited partnership established in the PRC on January 16, 2020 and its general partner is Beijing Tongde Tongxin Investment Center (Limited Partnership) (北京同德同鑫投資中心(有限合夥)) (“**Tongde Tongxin**”). The general partner of Tongde Tongxin is Tongde Qianyuan. As of the Latest Practicable Date, the only limited partner of Zhongheng Tongde is Guangxi Wuzhou Zhongheng Group Co., Ltd (廣西梧州中恒集團股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600252.SH), holding approximately 98% partnership interest in Zhongheng Tongde.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(ii) *Huiyou Xingyao*

Huiyou Xingyao is a limited partnership established in the PRC on September 24, 2020 and its general partner is Nanning Yaoyou Business Consulting Partnership (Limited Partnership) (南寧曜友商務諮詢合夥企業(有限合夥)) (“**Nanning Yaoyou**”). The general partner of Nanning Yaoyou is Tongde Qianyuan. As of the Latest Practicable Date, Huiyou Xingyao had 19 limited partners, the largest of which was Chongqing Lummy Pharmaceutical Co., Ltd. (重慶萊美藥業股份有限公司) (stock code: 300006.SZ), holding approximately 26.55% partnership interest in Huiyou Xingyao.

(iii) *Gongqingcheng Huiyou*

Gongqingcheng Huiyou is a limited partnership established in the PRC on June 23, 2021 and its general partner is Gongqingcheng Yaoyou Investment Center (Limited Partnership) (共青城曜友投資中心(有限合夥)) (“**Gongqingcheng Yaoyou**”). The general partner of Gongqingcheng Yaoyou is Tongde Qianyuan. As of the Latest Practicable Date, Gongqingcheng Huiyou had 13 limited partners, the largest of which was Peng Zhongxi (彭忠喜), holding 25.00% partnership interest in Gongqingcheng Huiyou.

Zhongheng Tongde, Huiyou Xingyao and Gongqingcheng Huiyou are investment arms of Tongde Qianyuan which focuses on investment and industrial mergers and acquisitions in innovative drugs, biotechnology and innovative medical device industries. As of the Latest Practicable Date, as confirmed by Tongde Qianyuan, the total assets managed by Tongde Qianyuan was approximately RMB314.6 million.

To the best knowledge of the Directors, save as disclosed above, each of Zhongheng Tongde, Huiyou Xingyao, Gongqingcheng Huiyou and Tongde Qianyuan, each of their ultimate beneficial owners, and each of their general partners and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Dr. Guo Hongwei

Dr. Guo Hongwei (郭宏偉) is an individual investor and a non-executive Director. For further details on his biography, please refer to the section headed “Directors, Supervisors and Senior Management” in this document.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

BGI Co-win Fund I

BGI Co-win Fund I is a limited partnership established in the PRC on December 2, 2016 and its general partner is BGI Co-win (Shenzhen) Private Equity Investment Fund Management Co., Ltd (華大共贏(深圳)股權投資基金管理有限公司) (“**BGI CoWin**”), which was in turn owned as to approximately 34.97% by BGI Shenzhen Co., Ltd. (深圳華大基因科技有限公司) and as to approximately 33.79% by Shenzhen Huao Capital Management Co., Ltd. (深圳華澳資本管理有限公司) as of the Latest Practicable Date. BGI Shenzhen Co., Ltd. was owned as to approximately 85.30% by Wang Jian (汪建) and Shenzhen Huao Capital Management Co., Ltd. was owned as to approximately 72% by Liu Yu (劉宇) as of the Latest Practicable Date. As of the Latest Practicable Date, BGI Co-win Fund I had 10 limited partners, the largest of which was Beihai Gofar Chuanshan Biological Co., Ltd. (北海國發川山生物股份有限公司) (stock code: 600538.SH), holding approximately 27.03% partnership interest in BGI Co-win Fund I. BGI CoWin is a private equity fund management institution established by a well-known professional investment team in the field of life science and healthcare. The management team of BGI CoWin has more than 15 years of investment and project incubation experience, has experienced the full cycle of fundraising, investment, management and exit of the fund, and has established a mature investment management system. The core team of BGI CoWin has been tracking medical fields such as gene technology, biomedicine and medical devices for a long time. As of the Latest Practicable Date, as confirmed by BGI CoWin, BGI CoWin has invested in more than 20 life science projects, with an asset exceeding RMB2 billion.

To the best knowledge of the Directors, save as disclosed above, each of BGI Co-win Fund I, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Sanhua Hongdao

Sanhua Hongdao is a limited partnership established in the PRC on September 27, 2016 and its executive partner is Zhang Shaobo (張少波). As of the Latest Practicable Date, Sanhua Hongdao had three partners and the largest limited partner is Sanhua Holding Group Co., Ltd. (三花控股集團有限公司) (“**Sanhua Holding**”), holding approximately 87.77% partnership interest in Sanhua Hongdao. As of the Latest Practicable Date, Sanhua Holding was owned by more than 40 shareholders with each of them holding less than 30% of its equity interest. Sanhua Hongdao is mainly engaged in equity investment, domestic and foreign mergers and acquisitions, and capital operation of listed companies, investing in enterprises at all stages of development with an annual investment scale of RMB1 billion as confirmed by Sanhua Hongdao.

To the best knowledge of the Directors, save as disclosed above, each of Sanhua Hongdao, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Hainan Weifeng

Hainan Weifeng is a limited partnership established in the PRC on August 4, 2020 and its general partner is Mao Fengfeng (毛豐峰). As of the Latest Practicable Date, Hainan Weifeng had one limited partner, Pu Weijie (浦偉傑), holding 99.00% partnership interest in Hainan Weifeng. Hainan Weifeng is mainly engaged in internet information services, information technology consulting services, information consulting services and investment activities with own funds.

To the best knowledge of the Directors, save as disclosed above, each of Hainan Weifeng, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Zhuhai Shengyi

Zhuhai Shengyi is a limited partnership established in the PRC on December 8, 2020 and its general partner is Ma Gang (馬鋼). As of the Latest Practicable Date, Zhuhai Shengyi had two limited partners, Tan Weiliang (譚煒樑) and Ye Jianfeng (葉健鋒), each holding approximately 49.85% partnership interest in Zhuhai Shengyi. Zhuhai Shengyi is mainly engaged in investment activities with own funds, business management consulting, business management, information consulting services and social and economic consulting services.

To the best knowledge of the Directors, save as disclosed above, each of Zhuhai Shengyi, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Baiying Huizhi

Baiying Huizhi is a limited partnership established in the PRC on January 26, 2018 and its general partner is Wuhan Baiying Biological Industry Investment Management Co., Ltd. (武漢百贏生物產業投資管理有限公司) (“**Wuhan Baiying**”). As of the Latest Practicable Date, Wuhan Baiying was wholly owned by Wuhan Bio-techo Institution Management Co., Ltd. (武漢生物技術研究院有限公司) (“**Wuhan Bio-techo**”), which was in turn wholly owned by Wuhan Bio-techo Institution (武漢生物技術研究院). As of the Latest Practicable Date, Baiying Huizhi had four limited partners, the largest of which was Wuhan Bio-techo, holding 45.00% partnership interest in Baiying Huizhi. Baiying Huizhi is mainly engaged in non-securities equity investment activities and related advisory services. As of the Latest Practicable Date, as confirmed by Baiying Huizhi, the total assets managed by Wuhan Baiying was approximately RMB0.18 billion.

To the best knowledge of the Directors, save as disclosed above, each of Baiying Huizhi, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shaoshan Hongyu

Shaoshan Hongyu is a limited liability company established in the PRC on January 14, 2021, which was owned as to 30.00% by Xie Xiaoyu (謝曉宇) and 30.00% by Wu Zhihong (伍志洪) as of the Latest Practicable Date. The business scope of Shaoshan Hongyu is medical research and experimental development, bio-based materials technology R&D, bio-chemical products technology R&D, first-class medical devices retail and manufacturing of chemical products.

To the best knowledge of the Directors, save as disclosed above, each of Shaoshan Hongyu, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Hainan Boyou

Hainan Boyou is a limited partnership established in the PRC on December 7, 2020 and its general partner is Liu Dong (劉東). As of the Latest Practicable Date, Hainan Boyou had 4 limited partners, the largest of which was Shidai Weiye, holding approximately 31.13% partnership interest in Hainan Boyou. Shidai Weiye was owned as to 60.00% and 40.00% by Liu Dong and Liu Junting (劉俊亭), respectively, as of the Latest Practicable Date. Hainan Boyou is mainly engaged in business management, social and economic consulting services, information consulting services and information technology consulting services.

To the best knowledge of the Directors, save as disclosed above, each of Hainan Boyou, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Qianshan Xinrong

Qianshan Xinrong is a limited partnership established in the PRC on May 8, 2021 and its general partner is Beijing Qianshan Xinyuan Investment Management Co., Ltd. (北京千山信遠投資管理有限公司) (“**Qianshan Xinyuan**”). As of the Latest Practicable Date, Qianshan Xinyuan was wholly owned by Qianshan Capital Management Co., Ltd. (千山資本管理有限公司), which was in turn owned as to approximately 73.40% by Wang Cheng (王成). As of the Latest Practicable Date, Qianshan Xinrong had seven limited partners, the largest of which were Luan Fuxing (樂福星) and Jia Liu (賈劉), each holding approximately 23.67% partnership interest in Qianshan Xinrong. Qianshan Xinrong is a private equity fund of Qianshan Xinyuan which is mainly engaged in equity investment, investment management, investment consulting and business information consulting. As of the Latest Practicable Date, as confirmed by Qianshan Xinrong, Qianshan Xinyuan managed private funds with the total size of approximately RMB3 billion.

To the best knowledge of the Directors, save as disclosed above, each of Qianshan Xinrong, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Guangdong Xingyao

Guangdong Xingyao is a limited partnership established in the PRC on December 21, 2020 and its general partner is Camel Equity Investment Fund Management (Guangdong) Co., Ltd. (駱駝股權投資基金管理(廣東)有限公司) (“**Camel Equity**”). As of the Latest Practicable Date, Camel Equity was owned as to 50.10% by Guangdong Tianxing Investment Holding Co., Ltd. (廣東天星投資控股有限公司) (“**Guangdong Tianxing**”). Guangdong Tianxing was owned as to 37.50% by Liu Yong (劉勇) and 37.50% by Liu Lu (劉露) as of the Latest Practicable Date. As of the Latest Practicable Date, Guangdong Xingyao had 18 limited partners, with each of them holding less than 10% equity interests in Guangdong Xingyao. Guangdong Xingyao is an investment arm of Camel Equity which is mainly engaged in equity investment, investment management, asset management and other activities with private equity funds. As of the Latest Practicable Date, as confirmed by Camel Equity, the total investment scale of Camel Equity exceeded RMB1.1 billion.

To the best knowledge of the Directors, save as disclosed above, each of Guangdong Xingyao, its ultimate beneficial owners, and its general partner and limited partners (as the case may be) is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Guanggu Entities

Three limited liability companies controlled by the state-owned Wuhan East Lake New Technology Development Zone Management Committee (武漢東湖新技術開發區管理委員會) (“**East Lake Management Committee**”) made [REDACTED] Investments in the Company. Details of these three companies are set out as below.

(i) Guanggu New Technology

Guanggu New Technology is a limited liability company established in the PRC on October 16, 2014, which was owned as to approximately 98.59% by Wuhan Hi-Tech Holding Group Co., Ltd. (武漢高科國有控股集團有限公司) (“**Wuhan Hi-Tech**”) as of the Latest Practicable Date. Wuhan Hi-Tech is a limited liability company established in the PRC, which was wholly owned by the state-owned East Lake Management Committee as of the Latest Practicable Date. Guanggu New Technology is mainly engaged in investment activities with its own funds and asset management services for the investments with its own funds.

(ii) Guanggu Health

Guanggu Health is a limited liability company established in the PRC on October 28, 2020, which was wholly owned by Hubei Science and Technology Investment Group Co, Ltd. (湖北省科技投資集團有限公司) (“**Hubei Science & Technology Investment**”) as of the Latest Practicable Date. Hubei Science & Technology Investment is a limited liability company established in the PRC, which was wholly owned by the state-owned East Lake Management Committee as of the Latest Practicable Date. Guanggu Health is mainly engaged in investment activities with its own funds, asset management services for the investments with its own funds and business management consulting.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(iii) Guanggu Growth

Guanggu Growth is a limited liability company established in the PRC on April 8, 2011, which was owned as to approximately 49.09% by Wuhan Optics Valley Venture Capital Fund Co., Ltd. (武漢光谷創業投資基金有限公司) (“**Guanggu VC**”) and as to approximately 49.09% by Wuhan Optics Valley Technology Financing Guarantee Co., Ltd. (武漢光谷科技融資擔保有限公司) (“**Guanggu Financing Guarantee**”), respectively, as of the Latest Practicable Date. Guanggu VC is a limited liability company established in the PRC, which was owned directly as to 57.00% by Wuhan Optics Valley Financial Holding Group Co., Ltd. (武漢光谷金融控股集團有限公司) (“**Guanggu Financial Holding Group**”) as of the Latest Practicable Date. Guanggu Financing Guarantee is a limited liability company established in the PRC, which was owned as to 90.00% by Guanggu Financial Holding Group as of the Latest Practicable Date. Guanggu Financial Holding Group is a limited liability company established in the PRC and was owned as to approximately 54.61% by Hubei Science & Technology Investment, which was wholly owned by the state-owned East Lake Management Committee as of the Latest Practicable Date. Guanggu Growth is mainly engaged in venture capital, venture capital consulting and entrepreneurial management services.

To the best knowledge of the Directors, save as disclosed above, each of Guanggu New Technology, Guanggu Health, Guanggu Growth and their ultimate beneficial owners is an independent third party and has no relationship with any connected persons of the Company or other [REDACTED] Investors.

Compliance with Interim Guidance

On the basis that (i) the consideration for the [REDACTED] Investments was settled more than 28 clear days before the date of our first submission of the [REDACTED] form to the Stock Exchange in relation to the [REDACTED], and (ii) no special rights of the [REDACTED] Investors will exist after the [REDACTED], the Sole Sponsor has confirmed that the [REDACTED] Investments are in compliance with the Guidance Letter HKEX-GL29-12 issued in January 2012 and updated in March 2017 by the Stock Exchange and the Guidance Letter HKEX-GL43-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange.

PUBLIC FLOAT

Upon completion of the [REDACTED] and conversion of the [REDACTED] Shares into H Shares, assuming that [(i) [REDACTED] H Shares being issued in the [REDACTED]; (ii) the [REDACTED] is not exercised; and (iii) [REDACTED] Shares being converted to H Shares, based on an [REDACTED] of HK\$[REDACTED] per H Share (being the mid-point of the indicative [REDACTED] range), [REDACTED]% of the Company’s total issued Shares with a market capitalization of at least HK\$[REDACTED] will be held by the public as required under Rule 18A.07 of the Listing Rules.] The [REDACTED] Shares, representing approximately [REDACTED]% of our total issued Shares immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised) and the conversion of the [REDACTED] Shares into H Shares, will not count towards the public float for the purpose of Rule 8.08 of the Listing Rules after [REDACTED]. Except as stated above, all the H Shares directly held by other Shareholders will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Please see the table below for more details on Shares which will not be counted towards public float for the purpose of Rule 8.08 of the Listing Rules:

Shareholder	Number of Shares ⁽³⁾	Percentage of the total share capital of the Company immediately following completion of the [REDACTED] (assuming that the [REDACTED] is not exercised) and the conversion of the [REDACTED] Shares into H Shares
CSPC-NBP ⁽¹⁾	[REDACTED]	[REDACTED]
Yuan Qian ⁽²⁾	[REDACTED]	[REDACTED]
Wuhan Caizhi ⁽²⁾	[REDACTED]	[REDACTED]
Dr. Zhou Hongfeng ⁽²⁾	[REDACTED]	[REDACTED]
Guanggu New Technology ⁽²⁾	[REDACTED]	[REDACTED]
Dr. Zhou Pengfei ⁽²⁾	[REDACTED]	[REDACTED]
Caizhi No. 2 ⁽²⁾	[REDACTED]	[REDACTED]
Guanggu Health ⁽²⁾	[REDACTED]	[REDACTED]
Huiyou Xingyao ⁽²⁾	[REDACTED]	[REDACTED]
BGI Co-win Fund I ⁽²⁾	[REDACTED]	[REDACTED]
Gongqingcheng Huiyou ⁽²⁾	[REDACTED]	[REDACTED]
Guanggu Growth ⁽²⁾	[REDACTED]	[REDACTED]
Zhuhai Shengyi ⁽²⁾	[REDACTED]	[REDACTED]
Dr. Guo Hongwei ⁽²⁾	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]

(1) The [REDACTED] H Shares held by CSPC-NBP, a substantial Shareholder and therefore our core connected person, representing approximately [REDACTED]% of our total issued Shares immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised) and the conversion of the [REDACTED] Shares into H Shares, will not be counted towards public float for the purpose of Rule 8.08 of the Listing Rules.

(2) The [REDACTED] Shares held by our Shareholders, representing approximately [REDACTED]% of our total issued Shares immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), will not be considered as part of the public float as these [REDACTED] Shares will not be converted into H Shares following the completion of the [REDACTED].

(3) For the avoidance of doubt, both [REDACTED] Shares (comprising Domestic Shares and [REDACTED] Foreign Shares) and H Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares.

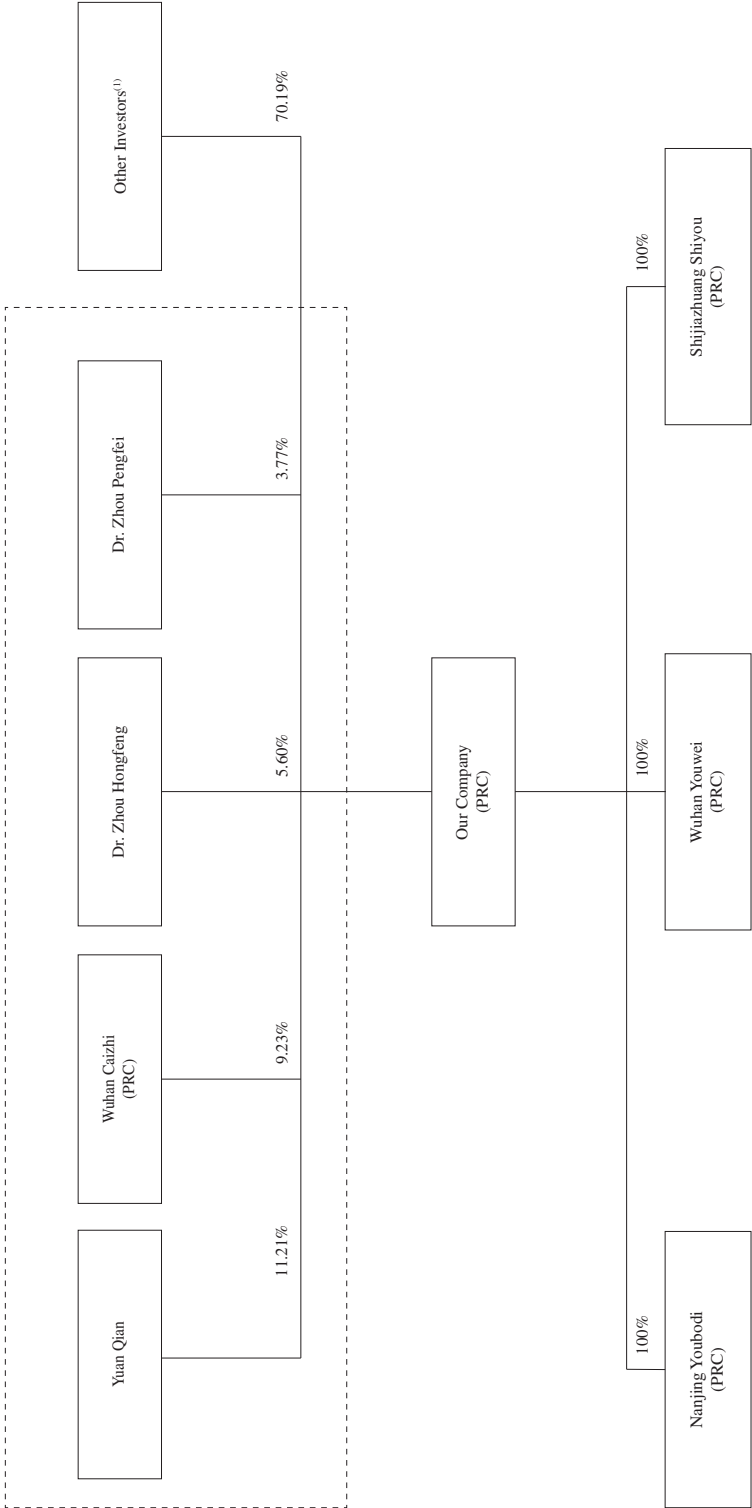
HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CORPORATE STRUCTURE

Corporate Structure Immediately before Completion of the [REDACTED]

The following chart illustrates the shareholding structure and simplified corporate structure of the Group immediately prior to the completion of the [REDACTED] and conversion of the [REDACTED] Shares into H Shares:

Total shareholding held/controlled by the AIC Parties: 29.81%



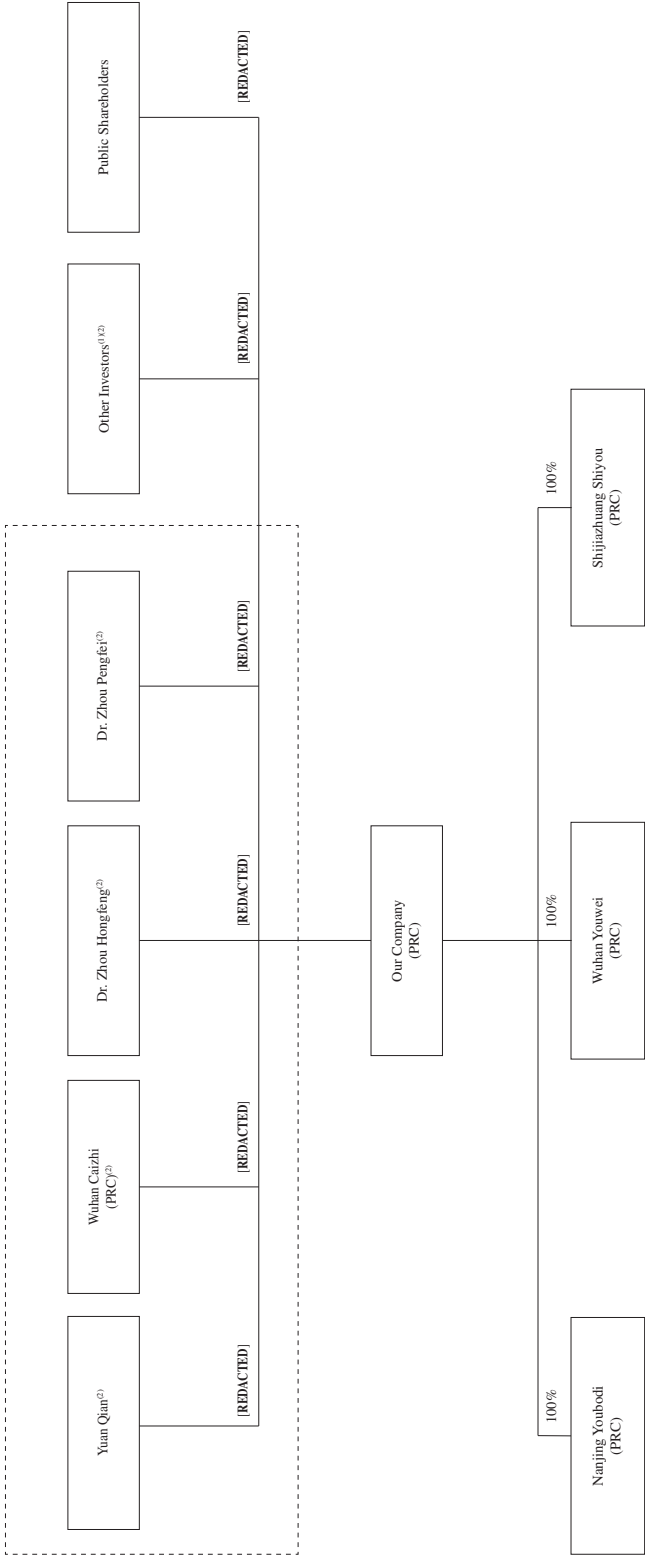
(1) For details on the other investors, please refer to the paragraphs headed “– [REDACTED] Investments – Summary of [REDACTED] Investments”, “– [REDACTED] Investments – Capitalization of the Company” and “– [REDACTED] Investments – Information about our [REDACTED] Investors” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Corporate Structure Immediately Following Completion of the [REDACTED]

The following chart illustrates the shareholding structure and simplified corporate structure of our Group immediately following the completion of the [REDACTED] and conversion of the [REDACTED] Shares into H Shares (assuming the [REDACTED] is not exercised):

Total shareholding held/controlled by the AIC Parties: [REDACTED]



(1) For details on the other investors, please refer to the paragraphs headed “– [REDACTED] Investments – Summary of [REDACTED] Investments”, “– [REDACTED] Investments – Capitalization of the Company” and “– [REDACTED] Investments – Information about our [REDACTED] Investors” in this section.

(2) The total of [REDACTED] Shares held by Yuan Qian, Wuhan Caizhi, Dr. Zhou Hongfeng, Guanggu New Technology, Dr. Zhou Pengfei, Caizhi No. 2, Guanggu Health, Huiyou Xingyao, BG1 Co-win Fund I, Gongqingcheng Huiyou, Guanggu Growth, Zhuhai Shengyi and Dr. Guo Hongwei, and the [REDACTED] H Shares held by CSPC-NBP will not be counted towards public float for the purpose of Rule 8.08 of the Listing Rules. For more details, please refer to the paragraphs headed “– Public Float” in this section.

BUSINESS

OVERVIEW

We are a biotechnology company dedicated to developing BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases.

Founded in 2010, we have designed and developed a pipeline of seven clinical-stage drug candidates. As of the Latest Practicable Date, five of our seven clinical-stage drug candidates were BsAbs designed for cancer treatment or cancer-associated complications such as MA and MPE. In particular, we have been focusing on the development of the T cell-engaging BsAbs, including M701, M802 and Y150, and the development of the TME-targeted BsAbs, including Y101D and Y332. Our Core Product, M701, is a recombinant BsAb that targets human EpCAM-expressing cancer cells and human CD3-expressing T cells. We completed a Phase I clinical trial of M701 in treating MA in January 2022. We are currently conducting a Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) in MA patients. In addition, we commenced a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP OR MARKET OUR CORE PRODUCT OR ANY OF OUR PIPELINE PRODUCTS.

Our Platforms

Equipped with our advanced platform technologies and strong R&D capability, we are at the forefront in discovering and developing drug candidates for the treatment of cancer and age-related ophthalmologic diseases. We have strategically developed four innovative platforms, including self-developed YBODY[®] platform, Check-BODY platform, and Nano-YBODY[™] platform, and UVAX[®] platform developed in collaboration with WIV.

- Our YBODY[®] platform is a BsAb platform that focuses on the development of asymmetric human immunoglobulin G (IgG)-like BsAbs with the structure of single-chain variable fragment – antigen-binding fragment – crystallizable fragment (scFv-Fab-Fc structure). The BsAbs with scFv-Fab-Fc structure developed by the YBODY[®] platform have unique features, including (i) favorable safety profile with low cytokine release syndrome-related toxicity due to their reduced affinity to human immune cells, (ii) high drug product purity of 99%, (iii) minimized mispairing between the heavy chains and light chains of BsAbs, (iv) favorable pharmacokinetics (PK) and pharmacodynamics (PD) profile, and (v) high stability. Based on YBODY[®] platform, we have developed three T cell-engaging BsAbs, namely M701, M802 and Y150. There were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide

BUSINESS

pipeline and one pipeline of other proteins according to public information; and Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into clinical development in China.

- Our Check-BODY platform is designed to develop symmetric tetravalent BsAbs. Both Fab and Fv fragments of a Check-BODY molecule show high affinity to the targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like monoclonal antibodies (mAbs) and therefore is easier to achieve. We are able to develop Check-BODY molecules with consistent high quality in multiple batches, and can easily scale up the production of Check-BODY molecules. We have discovered and developed Y101D, a PD-L1 $\times$ TGF- β BsAb, based on the technologies of our Check-BODY platform.
- Our Nano-YBODY™ platform is designed to develop symmetric tetravalent BsAbs based on single-domain antibodies. The well-designed structure enables Nano-YBODY™ molecules to achieve higher binding affinity, better stability, lower immunogenicity and higher production yield than other BsAbs. We have discovered and developed Y400 and Y332 based on the technologies of our Nano-YBODY™ platform. As a testament to our strong R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. For more details, please refer to the paragraphs headed “– Collaboration Agreements – Collaboration with CMS Vision” in this section.
- Our UVAX® platform is a unique immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our proprietary BsAb engineering technologies. We utilize our UVAX® platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield CHO expression and antibody-like purification systems. We have discovered and developed Y2019 based on the technologies of the UVAX® platform.

These platforms serve as an engine for our continuous endeavor to deliver new drug candidates, potential drug candidates we may develop in the future utilizing the molecular structures and CMC processes of the platforms. To protect our proprietary technologies and maintain our competitive advantages, we have built a comprehensive patent portfolio for our platforms. Leveraging our platform technologies, we are able to design and generate different antibody structures, and therefore can quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways.

BUSINESS

Our Business Model

All of our drug candidates and platform technologies are in-house developed, except for Y2019 and UVAX[®] platform which we develop in collaboration with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV). Our core business model is to in-house discover, develop and commercialize BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases.

Strategic Focus on BsAb-based Therapies

We have been dedicated to developing BsAb-based therapies since our inception in 2010. As of the Latest Practicable Date, five of our seven pipeline drug candidates were BsAbs designed for the treatment of some of the most significant cancer types as well as cancer-associated complications such as MA and MPE.

We carefully select potential targets for our BsAbs, and have adopted a differentiated clinical development strategy for our drug candidates. In particular, we have been focusing on the development of the T cell-engaging BsAbs, including M701, M802 and Y150. We initiated the R&D for M802 back to 2012 and obtained China’s first IND approval for in-house developed BsAb for M802. The R&D of our Core Product, M701, commenced in 2013, and we obtained China’s second IND approval for in-house developed BsAb for M701. We have also been focusing on the development of the tumor microenvironment (TME)-targeted BsAbs, and are developing Y101D and Y332.

For more details about our key development milestones for BsAbs for cancer treatment, please refer to the paragraphs headed “History, Development and Corporate Structure – Milestones” in this document.

During the Track Record Period, we have invested a significant portion of our efforts and financial resources in the development of BsAbs designed for cancer treatment. In 2021 and 2022, the R&D expenses attributable to the five BsAbs for the treatment of cancer and its complications in our pipeline amounted to RMB58.2 million and RMB80.4 million, respectively.

Commitment to BsAb-based Therapies

To fulfill our mission to discover and develop innovative drugs for the healthier lives of patients, we are committed to the continuous development and commercialization of BsAb-based therapies. We will continue to rapidly advance the development of our drug candidates for cancer treatment and invest more resources in the clinical development and pre-clinical studies of these drug candidates. We plan to use a significant portion of our [REDACTED] from the [REDACTED] for ongoing and planned clinical trials, preparation for registration filings, and planned commercial launch (including sales and marketing activities) of our drug candidates for cancer treatment.

BUSINESS

R&D Capabilities Fueled by Technology Platforms

Our ability to design and develop BsAbs is largely driven by our solid core technology platforms, namely YBODY[®], Check-BODY and Nano-YBODY[™]. M701, Y150 and M802 were designed and generated by YBODY[®], Y101D was designed and generated by Check-BODY, while Y332 and Y400 were generated by Nano-YBODY[™]. Leveraging our advanced platform technologies, we are able to design and generate different antibody structures.

For more details about our R&D capability and technology platforms, please refer to the paragraphs headed “– Our R&D Platform” in this section.

Strategic Collaborations

To complement our internal efforts, we have entered into collaboration arrangements with third parties in relation to the development of our drug candidates. For details, please refer to the paragraphs headed “– Collaboration Agreements” in this section. In the future, we will continue to seek strategic collaborations with resourceful partners and form additional strategic alliances or other collaborations. We are not currently engaged in negotiations with third parties on strategic collaborations.

Business Strategies to Navigate Pricing Pressure and Competition

We face pricing pressure for our BsAb drug candidates due to fierce competition in the market. Current medical treatment methods for MA and MPE, primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature. To maximize the market potential of M701 after its commercialization, we will adopt a pricing strategy for M701 with an aim to provide affordable drugs to patients and to benefit the patients. We will take into consideration clinical demands by MA and MPE patients, clinical value of M701, our market share, the competitive landscape and the price level of other available treatment options for MA or MPE in the relevant market. Furthermore, we may also face pricing pressure for our BsAb drug candidates to be included in the National Reimbursement Drug List (NRDL) in China due to their high costs of development and manufacturing. In China, prices of pharmaceutical products are currently determined mainly by market competition. 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. In addition, we may face competition from international and Chinese biopharmaceutical conglomerates who may operate on lower margins based on their economies of scale.

BUSINESS

To navigate such pricing pressure and competition, we (i) develop our Core Product, M701, with differentiated market positioning for the treatment of MA and MPE, (ii) maintain clinical dosages of our drug candidates at the microgram or milligram level, ensuring that each treatment course requires minimal medication quantities, thus lowering costs of treatment of our drug candidates and balancing patient affordability with our profitability, (iii) develop stable, high-yield processes under our proprietary technology platforms, including YBODY[®], Check-BODY and Nano-YBODY[™], to produce high-purity BsAb, and (iv) seek strategic collaborations and contract part of our manufacturing process to CMOs/CDMOs to reduce upfront investment costs.

Pipeline of Drug Candidates

We have designed and developed a pipeline of seven clinical-stage drug candidates. We strategically select potential targets for our drug candidates, and focus on the therapeutic areas with market potentials where fewer market players have expertise and resources. In particular,

- We have strategically focused on the development of the T cell-engaging BsAbs. We have developed three T cell-engaging BsAbs, namely M701, M802 and Y150;
- We have adopted the therapeutic strategy towards the efficient targeting of TME. TME plays a critical role in tumor initiation, development and progression, and therefore is becoming an emerging treatment target for cancer. We are developing two drug candidates targeting TME, namely Y101D and Y332; and
- We are developing Y400, a targeted therapy for the treatment of age-related ophthalmologic diseases.

BUSINESS

The following pipeline chart summarizes the development status of our selected drug candidates:

Candidate ¹	Target	Technology Platform	Type	Regimen	Indication	Pre-clinical	IND	Phase I	Phase II	Phase III/ Pivotal	Commercial Rights	Current Status/ Upcoming Milestone
★ M701	EpCAM×CD3	YBODY®	BsAb	Mono	Malignant ascites						Global	Phase II commenced in Dec 2021; Expect to initiate Phase III/pivotal trial in Q1 2024 and submit the BLA in Q1 2025
					Malignant pleural effusion						Global	Phase Ib/II commenced in Nov 2022; Expect to initiate Phase III/pivotal trial in Q3 2024 and submit the BLA in Q4 2025
					Solid tumor						Global	Expect to file IND application in Q1 2024 and initiate Phase III in Q2 2024
Y101D	PD-L1×TGF-β	Check-BODY	BsAb	Mono	Solid tumors						Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q4 2023
				Combo with gemcitabine and albumin paclitaxel	Pancreatic cancer						Global	Phase Ib/II commenced in Feb 2023; Expect to complete Phase Ib/II in Q3 2024 and initiate Phase III in Q4 2024
				Combo with bevacizumab	Hepatocellular carcinoma and other advanced solid tumors						Global	Phase Ib/II commenced in Mar 2023; Expect to complete Phase Ib/II in Q2 2025
				Combo with chemotherapy ²	Small cell lung cancer						Global	Expect to file IND application in Q3 2023; Expect to initiate Phase Ib/II in Q1 2024
Y150	CD38×CD3	YBODY®	BsAb	Mono	Relapse or refractory multiple myeloma						Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q2 2024
				Combo with lenalidomide	Relapse or refractory multiple myeloma						Global	Expect to file IND application after the completion of the Phase II portion of Phase Ib/II clinical trial of Y150 monotherapy for rMM
Y2019 ⁴	SARS CoV-2 RBD homodimer	UVAX®	Vaccine	Mono	COVID-19						Global	Completed Phase Ia
M802	HER2×CD3	YBODY®	BsAb	Mono	HER2-positive solid tumors						Global	Completed Phase I
Y332	VEGF×TGF-β	Nano-YBODY™	BsAb	Mono	Solid tumors						Global	IND application approved in Apr 2023; Expect to initiate Phase I in Q3 2023
Y400	VEGF×ANG2	Nano-YBODY™	BsAb	Mono	wAMD, DME and other ocular neovascularization related diseases						Global ⁴	IND application approved in Apr 2023
★ Core Product Clinical Stage Pre-clinical Stage												

- Notes:
- (1)
 - (2)
 - (3)
 - (4)
 - (5)

Except for Y2019, all of our drug candidates are in-house developed. Specific combination drug(s) of the trial will be decided prior to the commencement of the trial. We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluates the safety and tolerability of Y2019 in healthy adults, and obtained ethical committee approval for the Phase Ia clinical trial. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase Ia clinical trial for Y2019. We have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China. For more details, please refer to the paragraphs headed “- Collaboration Agreements – Collaboration with CMS Vision” in this section.

Some of our drug candidates are not included in the pipeline chart as they are at the early preliminary stage.

Abbreviations: Mono refers to monotherapy; Combo refers combination therapy; EpCAM refers to epithelial cell adhesion molecule; CD3 refers to cluster of differentiation 3; PD-L1 refers to programmed death ligand 1; TGF-β refers to transforming growth factor-β; CD38 refers to cluster of differentiation 38; COVID-19 refers to coronavirus disease 2019; RBD refers to recombinant receptor-binding domain; HER2 refers to human epidermal growth factor receptor 2; VEGF refers to vascular endothelial growth factor; ANG2 refers to angiopoietin-2; wAMD refers to wet age-related macular degeneration; DME refers to diabetic macular edema.

BUSINESS

M701

M701, our Core Product, is a recombinant BsAb that targets EpCAM-expressing cancer cells and T cell surface antigen CD3. We are developing M701 for the treatment of MA and MPE. M701 also has the potential to treat various solid tumor. The M701 intraperitoneal infusion takes approximately one hour and it is in line with the industry standard.

The market size of MA therapies grew from RMB9.8 billion in 2017 to RMB10.7 billion in 2021 and is expected to grow and reach RMB12.4 billion in 2025 and RMB14.7 billion in 2030, and the market size of MPE therapies grew from RMB10.8 billion in 2017 to RMB11.6 billion in 2021 and is expected to grow and reach RMB13.2 billion in 2025 and RMB15.3 billion in 2030.

We are currently conducting a Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA. In this clinical trial, subjects receive systematic treatment for the treatment of cancer. As these subjects are suffering from MA as a result of their cancer, they are designed to receive M701 monotherapy for the treatment of MA. As advised by our PRC Legal Advisor, pursuant to the “Clinical Trial Technical Guidance Principles for Combination Therapy of Anticancer Drugs” (《抗腫瘤藥物聯合治療臨床試驗技術指導原則》) issued by the CDE, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MA), this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MA. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MA in the first quarter of 2024. The expected BLA submission time will be in the first quarter of 2025 and the expected commercial launch time will be in the fourth quarter of 2025. In addition, we commenced a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MPE in the third quarter of 2024. The expected BLA submission time will be in the fourth quarter of 2025 and the expected commercial launch time will be in the second quarter of 2026. Furthermore, we expect to commence a Phase I/II clinical trial for treatment of solid tumor in the second quarter of 2024.

Y101D

Y101D, a recombinant anti-PD-L1 and anti-TGF- β humanized BsAb, is being developed for the treatment of solid tumors.

BUSINESS

According to the CDE and the ClinicalTrials.gov websites, Y101D is the only PD-L1 × TGF-β symmetric tetravalent BsAb that has entered into clinical development globally. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document. Based on our pre-clinical studies, the anti-TGF-β fragment of Y101D has better stability and biological activity than TGF-β trap *in vivo*. Y101D is strategically designed to simultaneously inhibit the PD-1/PD-L1 axis and the TGF-β signaling pathways, thus having the potential to unleash a synergistic anti-tumor activity and relieve drug resistance. We are currently evaluating Y101D in a Phase I clinical trial for the treatment of metastatic or locally advanced solid tumors, and interim results of this Phase I clinical study show an encouraging safety and efficacy profile for Y101D. We also commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer in February 2023. We commenced for a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of HCC and other advanced solid tumors in March 2023. In addition, we plan to submit IND application for Y101D for the treatment of SCLC in the third quarter of 2023 initiate a Phase Ib/II clinical trial of Y101D in combination with chemotherapy for the treatment of SCLC in the first quarter of 2024.

Y150

Y150 is a recombinant anti-CD38 and anti-CD3 humanized BsAb. We are developing Y150 for the treatment of rrMM in a Phase I clinical trial. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We also plan to initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM.

According to the CDE website, Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into the clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document. Y150 is well-designed to bind to both CD38 on multiple myeloma (MM) tumor cells and CD3 on T cells, inducing the activation of the T cells, improving the targeting of activated T cells, and allowing the activated T cells to attack the target tumor cells.

BUSINESS

Y2019

Y2019 is a recombinant receptor-binding domain (RBD)-dimer subunit SARS-CoV-2 vaccine candidate for COVID-19.

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluated the safety and tolerability of Y2019 in healthy adults aged 18 years or older, and have obtained satisfactory 7-day and 90-day safety data post immunization. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

M802

M802 is an anti-HER2 and anti-CD3 humanized BsAb. We are developing M802 for the treatment of HER2-positive solid tumors.

We have completed a Phase I clinical trial for M802 in China. We will consider exploring potential out-licensing opportunities of M802 in the global market. M802 displays significant cytotoxicity to some Herceptin-resistant breast cancer cells (JIMT-1, MDA-MB-231), indicating an emerging treatment for HER2-positive and/or Herceptin-resistant breast cancer patients. M802 binds to HER2 with high affinity, and binds to CD3 receptor with lower affinity, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. Data obtained from the Phase I clinical trial of M802 also indicates that M802 has a favorable safety profile.

Y332

Y332, a recombinant anti-VEGF and anti-TGF- β BsAb, is being developed for the treatment of a variety of solid tumors. We received IND approval for Y332 for metastatic or locally advanced solid tumors in April 2023.

In pre-clinical studies, Y332 shows high affinity to both VEGF and TGF- β , favorable bioactivity and stability, and demonstrates encouraging anti-tumor effects. Y332 can also be used in combination of immune checkpoint inhibitors to deliver an enhanced anti-tumor effect. There is currently only one VEGF $\times$ TGF- β BsAb, namely ZGGS18, that has entered into clinical development in China. Based on our internal pre-clinical studies, Y332 shows favorable bioactivity and stability.

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Y400

Y400 is a recombinant anti-VEGF and anti-ANG2 BsAb. The CMC studies for Y400 have been completed and the CDE approved the IND application for Y400 in April 2023.

In our *in vitro* experiment, Y400 has shown an encouraging efficacy profile. Y400 also has a high concentration formulation which is an important factor for the success of such ophthalmic drugs.

As a testament to our strong R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. For more details, please refer to the paragraphs headed “– Collaboration Agreements – Collaboration with CMS Vision” in this section.

We aim to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. According to the WHO website, cancer is the second-leading cause of death globally. The oncology drug market in China has expanded significantly in the past several years, primarily driven by increasing cancer incidences, improving affordability of marketable drugs and technological progress in the treatment paradigm. According to the Global Cancer Observatory (GLOBOCAN), International Agency for Research on Cancer (IARC) and National Central Cancer Registry of China (NCCR), the annual cancer incidence in China is expected to increase from approximately 4.7 million in 2021 to approximately 5.8 million in 2030. Our current pipeline drug candidates address some of the most significant cancer types, as well as cancer-associated complications such as MA and MPE. Therefore, we believe we are well-positioned to capture the market opportunities in the PRC oncology drug market.

According to the National Bureau of Statistics of China, the population of senior people aged at or above 65 years old in China is expected to increase from approximately 200 million in 2021 (approximately 14% of all China’s population) to approximately 317 million in 2030 (approximately 22% of all China’s population). China has one of the fastest-growing aging populations in the world, resulting in an increasing clinical demand for preventive and therapeutic drugs for age-related ophthalmologic diseases.

To fulfill our mission to discover and develop innovative drugs for the healthier lives of patients, we are committed to the continuous development and commercialization of BsAb-based therapies. By advancing the R&D of our drug candidates, we strive to deploy our innovation engine in the fight against cancer and age-related ophthalmologic diseases for the benefit of patients to improve their quality of life and survival rate.

BUSINESS

OUR STRENGTHS

A pioneer standing at the forefront of the development of BsAbs in China

We are a pioneer standing at the forefront of the development of BsAbs in China. We have strategically developed YBODY®, a BsAb platform that focuses on the development of asymmetric IgG-like BsAbs with scFv-Fab-Fc structure. M701, our Core Product, is an EpCAM × CD3 BsAb that focuses on the treatment of MA and MPE. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins; and Y150, the only CD38-targeting and T cell-engaging BsAb to have entered into clinical development in China, according to the CDE website. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

We have strategically designed and built our pipeline to focus on the development of new BsAb drugs. In recent years, BsAbs have attracted increasing interest in scientific and clinical research for the treatment of cancer. Multiple signaling pathways are involved in tumor cell development. Even if a mutationally activated pathway can be blocked by an inhibitor, tumor cells may evade the inhibitor by activating other pathways. Therefore, through targeting two different antigen binding sites to block two different signaling pathways, or through enhanced binding affinity to prevent the tumor immune escape, BsAbs can deliver potent and tumor-specific killing effect. The therapeutic effect of BsAbs, such as T cell engaging BsAbs, are 100- to 1,000-fold stronger than that of mAbs. Furthermore, BsAbs have a wide range of applications in tumor immunotherapy. However, the safety and efficacy of BsAbs in treating cancer and its complications compared to the current treatments for these diseases remain to be substantiated in clinical applications. In addition to cancer treatment, BsAbs also have potential in treating other diseases, such as ophthalmology and hemophilia.

We strategically select potential targets for our BsAbs, and have adopted a differentiated clinical development strategy for our drug candidates. We have focused on the development of the T cell-engaging BsAbs, including M701, M802 and Y150 that can destruct tumor cells through T cell activation. T cell-engaging BsAb is a new class of therapeutic agents designed to simultaneously bind to T cells and tumor cells via tumor-cell specific antigens in immunotherapy. In addition, we are also focusing on the development of the TME-targeted BsAbs, including Y101D and Y332. TME plays a critical role in tumor initiation, development and progression, and therefore is becoming an emerging treatment target for cancer.

BUSINESS

Our ability to design and develop BsAbs is largely driven by our solid core technology platforms, namely YBODY[®], Check-BODY and Nano-YBODY[™]. The design and production of BsAbs present a unique set of challenges due to the presence of BsAb-specific byproducts, such as mispaired products, undesired fragments and higher levels of aggregates, that are otherwise absent or present in lower levels in mAb cells. Leveraging our advanced platform technologies, we are able to overcome these technical difficulties and have made the following achievements in developing BsAbs:

- *Minimum mismatches and high purity.* The main challenge in the development of BsAbs is that there are two types of chains, heavy and light, and it is difficult yet critical to prevent mismatches. We have successfully addressed this challenge by utilizing optimized technologies in the design of our BsAbs. For instance, we introduced the Knobs-into-Holes and salt-bridge technologies in the Fc modification to disfavor the formation of homodimers and achieve the desired heterodimeric BsAbs. Furthermore, by utilizing the proprietary design of the scFv segment, we are able to completely avoid the mismatch of heavy chains and light chains for YBODY[®] molecules. We can achieve 99% product purity of the YBODY[®] molecules by (a) achieving over 90% accurate pairing of heavy chains based on the technologies of the YBODY[®] platform and (b) eliminating those less than 10% mismatches in heavy chains by applying the traditional protein purification process techniques.
- *High stability.* BsAbs are engineered artificial antibodies, and thus are more unstable than mAbs. We utilize advanced antibody engineering technologies to design the optimized structure of our BsAbs and effectively achieve high stability of these BsAbs.
- *Minimum immunogenicity.* With an increasing number of BsAbs entering into clinical development, recent data highlights immunogenicity as an emerging challenge in the development of such biologics. Repetitive administration of these protein-based therapeutics to immunocompetent patients elicit immune responses in the form of anti-drug antibodies, which in turn impact their pharmacological properties and may trigger adverse events. We have implemented a drug-specific immunogenicity risk assessment strategy to minimize immunogenicity risks in our drug candidates. Through *in vitro* and *in vivo* experiments, we selectively choose the candidates with lowest level of immunogenicity risks for next-step research and development.
- *Effective target selection and binding.* We conduct thorough evaluations for various targets, and select the optimized targets with clinical and commercial potentials in developing our BsAbs. For instance, one of our focuses on the BsAb development is to develop the T cell-engaging BsAbs, which has potential in treating both

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hematological malignancies and solid tumors. The dual-targeting mechanism of these BsAbs enable them to target both TAAs on tumor cells and the CD3 receptor on the surface of T cells, bridging them together and activating T cells to kill the cancer cells.

With the increasing trend of population aging and growing cancer incidences in China, it is expected that the clinical demands for effective oncology drugs will increase significantly. The market size of the PRC oncology market has increased from approximately RMB139.4 billion in 2017 to approximately RMB231.1 billion in 2021, and is expected to reach approximately RMB651.3 billion in 2030. In particular, due to the encouraging efficacy and manageable safety profile, the market size of PRC therapeutic antibody drugs has increased from approximately RMB11.8 billion in 2017 to RMB58.4 billion in 2021, and is expected to reach RMB484.0 billion in 2030. With our strategically designed pipeline and our advanced platform technologies, we believe we are well-positioned to capture the growing market opportunities.

Advanced technology platforms fueling the research and development of drug candidates

Our advanced core technology platforms enable us to effectively select innovative targets, optimize molecule structure design and accelerate the drug development process. We have successfully built four proprietary technology platforms, including self-developed YBODY[®], Check-BODY and Nano-YBODY[™] platform, and UVAX[®] platform developed in collaboration with WIV. Leveraging the advanced technologies of these platforms, we are able to design and generate different antibody structures. As such, we can select targets and signaling pathways with clinical and commercial value and design and modify the structure of our BsAbs to bind such targets. Therefore, we are able to quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways, optimize the use of our resources and expertise, and achieve the maximized value of our pipeline candidates.

YBODY[®] Platform

Our in-house developed YBODY[®] platform is an innovative BsAb platform that focuses on the development of asymmetric human IgG-like BsAbs with scFv-Fab-Fc structure. The unique features of our YBODY[®] platform enable us to discover and develop BsAbs to target both TAAs of a variety of tumor cells and the receptors on the surface of human immune cells (such as T cells, NK cells and macrophages). We have discovered and developed three T cell-engaging BsAbs, including M701 (an EpCAM × CD3 BsAb), M802 (a HER2 × CD3 BsAb) and Y150 (a CD38 × CD3 BsAb), based on the technologies of our YBODY[®] platform.

YBODY[®] has an IgG-like structure, so it can provide good pharmacokinetics and pharmacodynamics. The well-designed structure of the asymmetrical YBODY[®] molecules features moderate affinity to human immune cells, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. The proprietary design of the scFv structure of YBODY[®] molecules is applied to avoid mispairing of heavy chains and light chains. Furthermore, we can easily identify the misassembled impurities of BsAbs through the

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asymmetry of the molecular weight and thus remove the impurities through the asymmetry of the molecular charge. In this way, we improve the efficiency of the desired dimerization and formation of YBODY[®] molecules.

Check-BODY Platform

Our in-house developed Check-BODY platform, a new generation immune checkpoint platform, is designed to develop innovative symmetric tetravalent BsAbs to direct toward the most prevailing targets, including dual immune checkpoints, immune checkpoint and cytokine, as well as the immune checkpoint and tumor microenvironment target. We have discovered and developed Y101D based on the technologies of our Check-BODY platform.

A Check-BODY molecule is composed of three segments: two Fab fragments from antibody A to target TAAs, two variable fragments from antibody B to target and activate the T cells to kill the tumor cells, and Fc fragments from human IgG with or without modification. We apply the genetic engineering technology to use protein linkers to connect the Fab fragments with Fv fragments and the Fc fragments, respectively, to achieve the ultimate symmetric tetravalent BsAb products. Both Fab and Fv fragments of a Check-BODY molecule show high affinity to the targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like mAbs and therefore is easier to achieve. Therefore, the product purity of Check-BODY molecules can reach over 90% by the one-step affinity chromatography.

Nano-YBODY[™] Platform

Our in-house developed Nano-YBODY[™] platform is a new generation BsAb platform developed by us in-house. The Nano-YBODY[™] platform is designed for the development of symmetric tetravalent BsAbs based on single-domain antibodies. We have discovered and developed two IND-enabling drug candidates, namely Y400 and Y332, based on the technologies of the Nano-YBODY[™] platform. We apply genetic engineering technology to connect the heavy chain of an IgG mAb with the variable domain of a heavy chain (VHH) of a single domain antibody to achieve the ultimate symmetric tetravalent BsAbs with an IgG-(VHH)₂ structure. Nano-YBODY[™] molecules show high affinity to both targets. These molecules also have favorable performance in production expression, purification yield, liquid formulation concentration, stability, solubility and shelf life.

UVAX[®] Platform

Our UVAX[®] platform, developed in collaboration with WIV, is a unique immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our proprietary BsAb engineering technologies. We utilize our UVAX[®] platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield CHO expression and antibody-like purification systems. We have discovered and developed Y2019 based on the technologies of the UVAX[®] platform. The immunogen of Y2019 is a homodimerized protein of which two RBD monomers are linked

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covalently by an interdomain disulfide bond at the C terminus of the RBD of the S protein. According to the design, the SARS-CoV-2 RBD gene (319–541 amino acid) is fused with the Fc gene of human IgG, and the DNA of the genes are constructed into the vector to express the RBD-Fc fusion protein. The Fc fragment of the fusion protein is then removed by thrombin digestion and purification to obtain the RBD homodimer protein as the immunogen of the vaccine. Therefore, UVAX[®] vaccines have high production expression, purification yield and stability.

Comprehensive Patent Protection

To protect our proprietary technologies and maintain our competitive advantages, we have built a comprehensive patent portfolio for our core technology platforms. In particular, as of the Latest Practicable Date, (a) we filed two PCT applications for our YBODY[®] Platform, and had entered into national phase in major markets, including seven granted patents in China, Canada, the U.S. and Japan, and six pending patent applications in China, Canada, Europe, Japan and South Korea; (b) we filed one PCT application for our Check-BODY Platform, and entered into national phase in major markets, including one granted patent in China, and six pending patent applications in China, the U.S., Canada, South Korea, Europe and Japan, and (c) we filed one PCT application for our general Fc mutation technology, and entered into national phase in major markets, including one granted patent in China, three pending patent applications in the U.S., Europe and Japan. We will continue to seek patent protections for our core technology platforms and drug candidates.

A strong pipeline of drug candidates with market potential leveraging our differentiated clinical development strategies

We have adopted a differentiated clinical development strategy to maximize the clinical and commercial value of our drug candidates. We strategically select potential targets for our drug candidates, and focus on the therapeutic areas with demands where fewer market players have expertise and resources.

Leading in developing T cell-engaging BsAbs in China

We have strategically focused on the development of the T cell-engaging BsAbs. We have developed three T cell-engaging BsAbs, namely M701, M802 and Y150. Although CD3-targeted BsAbs have shown promising effects in treating hematological tumors, such BsAbs have certain limitations in treating solid tumors. Our well-designed T cell-engaging BsAbs can overcome such limitations. The dual-targeting mechanisms of these BsAbs enable them to target both TAAs on solid tumor cells and the CD3 receptors on the surface of T cells, bridging them together and activating T cells to kill the cancer cells.

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M701 – a potentially standard treatment option for MA and MPE

M701, our Core Product, is an EpCAM × CD3 BsAb that focuses on the treatment of MA and MPE. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. We are evaluating M701 for the treatment of MA in a Phase II clinical trial and MPE in a Phase Ib/II clinical trial. MA and MPE occur in association with a variety of cancer types and raise significant treatment challenges.

The currently available treatment options include a multitude of different procedures with limited efficacy and a certain degree of risks. For example, according to the literature, diuretic therapy is only less than 50% effective in treating MA. Patients who fail to respond to diuretic therapy and nutritional support needed to undergo laparotomy for fluid release. Around 90% of patients have symptomatic relief, but this is maintained for an average of only approximately 10 days and generally needs to be repeated. Repeated massive puncture drainage carries the risk of reduced effective circulating blood volume, hyponatremia, renal dysfunction and hypoproteinaemia. Local chemotherapeutic drug therapy has an efficiency of only 40%-60% in treating MA. Closed drainage of the pleural cavity with a chest tube is only 11%-40% effective for 30 days to control MPE. The incidence of complications from pleural cavity atresia is up to more than 40%. Therefore, there remains a medical demand of MA and MPE patients for an effective therapy. As of the Latest Practicable Date, no BsAb has been approved for the treatment of MA or MPE in China, according to the CDE website. We believe that M701 has the potential to capture this market opportunity and address the medical demands.

Both MA and MPE are commonly found in various cancer types. To effectively address the challenges in treating MA and MPE and embrace the market opportunities, we have strategically selected EpCAM as the target on tumor cells. Abnormal EpCAM expression is regularly found in cancer patients who tend to develop MA and MPE, according to relevant research papers. EpCAM expression is highly tumor-specific as normal cells in the peritoneal compartment do not express EpCAM on their surface. According to relevant research papers, such as Went, P., et al. “Frequent high-level expression of the immunotherapeutic target EpCAM in colon, stomach, prostate and lung cancers.” British journal of cancer, high EpCAM expression is observed in approximately 90% of gastric cancer, approximately 60% of lung cancer, over 50% of ovarian cancer and approximately 50% of breast cancer. Therefore, EpCAM is deemed a particular suitable target for treating MA and MPE. With a clear mechanism of actions, and encouraging clinical results, we believe M701 has potential to become a standard treatment option for MA and MPE.

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Y150 – a candidate with innovative mechanism for rrMM patients

We are developing Y150, a CD38 × CD3 BsAb, for the treatment of rrMM. We are evaluating Y150 in a Phase I clinical trial. Despite the introduction of multiple therapies, MM remains incurable, and patients experience multiple relapses and/or become refractory to current standard-of-care treatments. CD38 is highly expressed in MM cells, making it a desirable target for innovative therapeutic antibodies. The MM incidence in China increased from 19.5 thousand in 2017 to 21.7 thousand in 2021, and is expected to further reach 27.7 thousand in 2030. The MM patients generally have a longer overall survival period, and thus need different therapies with diversified mechanisms of actions due to drug resistance, representing a need for new classes of therapies with innovative mechanisms of action. According to the CDE website, Y150 is the only CD38-targeting and T cell-engaging BsAb to have entered into clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. Outside of China, there is only one CD38 × CD3 BsAb, namely ISB-1342 of Ichnos Sciences, under development in a Phase I clinical trial. Besides that, SAR442257, an anti-CD38/CD28/CD3 antibody being developed by Sanofi, is also under clinical development, evidencing the therapeutic potentials of CD38 and CD3. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

M802 – targeting HER2-positive solid tumors to meet significant demands for second-line treatments

We are developing M802, a HER2 × CD3 BsAb, initially for the treatment of HER2-positive solid tumors. We have completed a Phase I clinical trial for M802. We will consider exploring potential out-licensing opportunities of M802 in the global market. The breast cancer incidence in China increased from approximately 315.2 thousand in 2017 to approximately 336.3 thousand in 2021, and is expected to further reach approximately 372.4 thousand in 2030. Patients with breast cancer generally have a longer overall survival period, and therefore need to receive multiple second-line treatments with different and innovative mechanism of actions. Furthermore, HER2 is also frequently observed in bladder cancer, pancreatic cancer, ovarian cancer and gastric cancer, representing a huge market with demands.

Strategic development of candidates targeting TME

We are adopting innovative therapeutic strategies towards an efficient targeting of tumor microenvironment (TME). The tumor mass consists of not only a heterogeneous population of cancer cells but also a variety of resident and infiltrating host cells, secreted factors and extracellular matrix proteins, collectively known as the TME. TME plays a pivotal role in tumor initiation, progression and therapeutic resistance by creating a dynamic interaction with cancer cells.

We are strategically developing two drug candidates targeting TME, namely Y101D and Y332.

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Y101D – overcoming the limitations of anti-PD-L1 antibodies

We are developing Y101D, a PD-L1 $\times$ TGF- β BsAb, for the treatment of solid tumors. We are evaluating Y101D in a Phase I clinical trial. Therapeutic antibodies that target PD-1/PD-L1 axis induce potent and durable anti-tumor responses in multiple types of solid tumors. However, only a subset of patients benefit from anti-PD-1/PD-L1 therapies. For instance, among various PD-1/PD-L1 approved indications, the overall response rate (ORR) for head and neck squamous cell carcinoma and liver cancer is less than 35% (i.e. over 65% of patients are primary refractory). Microsatellite stable type colorectal cancer, pancreatic cancer, and biliary cancer are less likely to benefit from and are not approved for PD-1/PD-L1 treatment; the median progression-free survival (PFS) for non-squamous and squamous lung cancer is 8-9 months; the median PFS for small cell lung cancer is only 5.2 months; and the median PFS for esophageal squamous cell carcinoma is only 6.9 months, indicating that these patients will develop resistance after treatment for 5-9 months. Y101D is strategically designed to simultaneously inhibit the PD-1/PD-L1 axis and the TGF- β signaling pathways, and has the potential to unleash a synergistic anti-tumor activity and relieve drug resistance. By simultaneously inhibiting the PD-1/PD-L1 axis and the TGF- β signaling pathways, Y101D restores the dysregulated anti-tumor immunity of cancer patients and establishes an immuno-supportive TME.

Y332 – unlocking the therapeutical potential for both VEGF and TGF- β pathways

Y332 is a VEGF $\times$ TGF- β BsAb for the treatment of solid tumors. By simultaneously targeting VEGF and TGF- β , Y332 unlocks the therapeutical potential of blockades for both pathways, synergistically transforming the immuno-suppressive TME of cancer patients and restoring their dysregulated anti-tumor immunity. We received IND approval for Y332 for metastatic or locally advanced solid tumors in April 2023. Y332 can also be used in combination with immune checkpoint inhibitors to deliver an enhanced anti-tumor effect.

A strategic focus on increasing age-related ophthalmologic diseases

We have strategically focused on the development of drug candidates to address the rapidly growing age-related ophthalmologic diseases. In particular, we have taken a collaborative approach to develop Y400, a VEGF $\times$ ANG2 BsAb. The CDE approved the IND application for Y400 in April 2023. VEGF and ANG2 are two important targets that can promote the proliferation and leakage of new blood vessels, as well as the formation of abnormal vascular structure, which will eventually lead to vision loss. As a BsAb simultaneously targeting VEGF and ANG2, Y400 is an emerging prospect for the treatment of wAMD, DME and other ocular neovascularization-related diseases when compared to currently prevailing anti-VEGF therapies. wAMD and DME patient incidence reached approximately 3.9 million and 7.1 million in China in 2021, accounting for approximately 1.9% and 3.5% of senior people aged at or above 65 years old in China.

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Efforts to combat COVID-19

The pandemic of COVID-19 caused by SARS-CoV-2 has raised new challenges around the globe. As of October 31, 2022, the global COVID-19 pandemic caused by the SARS-CoV-2 virus has resulted in approximately 630 million infections and 6.6 million deaths globally. It is critical to develop rapid viral detection technologies, therapeutics, and vaccines, to stop the relentless spread of COVID-19, and effective vaccines are widely considered to be the best approach. To combat COVID-19, we are taking a collaborative approach to develop Y2019. Through the application of our UVAX[®] platform technologies, Y2019 can elicit high titers of neutralizing antibodies after vaccine immunization, leading to durable immune response with long-term protection against SARS-CoV-2.

A robust and GMP-compliant CMC platform

We have established a robust and GMP-compliant chemistry, manufacturing and control (CMC) platform to leverage our extensive experience in the CMC for BsAbs with various structures. We believe such platform will serve as a solid foundation for our large-scale commercial production in the future. CMC refers to activities to properly define methods for manufacturing processes, product characteristics and testing, product storage and release to clinical usage in order to ensure that a pharmaceutical product is safe, effective and consistent among different batches. Although the discovery and protein engineering techniques of BsAbs are now relatively advanced, the development of BsAbs still faces many challenges in the CMC comparing to the development of typical mAb drugs, including low expression titer of the target BsAbs, more impurities to remove, less stability of the intermediates, and hurdles in process scale-up. Therefore, the execution of an appropriate CMC development strategy is vital to the success of the overall drug development program.

Our CMC strategies include evaluating the stability of the candidate BsAb molecules at the early development stage, choosing the monoclonal cells with high titer and high purity for BsAb production, tailoring purification methods fit for the molecule characteristics, and using sustainable scale-up strategies for large-scale production.

- *High expression level in cell line development.* We leverage the world’s leading CHO GS-KO expression system to design and produce various types of BsAbs with different structures. As such, we are able to obtain stable cell lines at high expression level.
- *High expression level in upstream process development.* To improve the titers of target BsAbs, we optimize the manufacturing process by adopting the Fed-Batch mode. With the optimized techniques, we are able to achieve the average expression level for Check-BODY molecules and Nano-YBODY[™] molecules of approximately 6.0g/L and 8.0g/L, respectively, far beyond the industry average in China.

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- *High purity in downstream development.* Through downstream development and optimization, we are able to achieve high purity of our BsAbs, which has led to a favorable safety profile of our candidates. The total yield of BsAbs in our purification process can reach 75%, and the purity of the drug substance can reach 99%, with low levels of impurities.
- *High concentration formulations development.* We are able to produce different types of formulation products, such as liquid and lyophilized dosage forms. Through the formulation screening and optimization, our BsAb formulations are able to reach a concentration rate of 140mg/ml with low product viscosity and great stability, exceeding the industry average in China.
- *Established analytical methods to expedite the CMC process.* We have developed more than 30 platform analytical methods to support our drug development. At the early stages of drug development, we apply these analytical methods to analyze molecular properties and characterize molecular structures, which can expedite sample testing and improve our development efficiency. At the CMC stage, the analytical methods are optimized by us to accommodate projects involving different BsAbs. As such, we are able to efficiently support and accelerate our product development and manufacturing process.
- *Compliance with global regulatory standards.* As drug development moves from concept to commercialization, the breadth and depth of CMC documentation required in regulatory submissions increases in parallel. Equipped with our advanced CMC platform, we are able to comply with GMP requirements and consistently deliver BsAbs in compliance with the requirements of the NMPA, the FDA and the EMA. Our strong CMC capabilities to meet global regulatory standards are evidenced by our receipt of NMPA and FDA IND approvals for our drug candidates, namely M701, M802, Y150 and Y101D.
- *Established and expanding manufacturing facility.* As of the Latest Practicable Date, we had a manufacturing base of approximately 1,400 square meters with a scale of 500L (two 200L bioreactors and two 50L bioreactors) for antibody production. While we already have sufficient manufacturing capability to meet the demands for Phase I to Phase II clinical development, we plan to continue to enhance our manufacturing capability.

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Visionary, seasoned and execution-driven management and R&D teams with a proven track record

Our core management team is composed of industry veterans with an average of more than ten years of experience and a track record of successful discovery, development and commercialization of innovative drugs. As a pioneer standing at the forefront of the development of BsAbs in China, we, as one team led by our senior management, strive to deliver innovative drugs with aligned aspirations to address large medical demands. Leveraging our team’s strong, comprehensive and complementary capability to consistently advance the development of our drug candidates, implement differentiated yet effective clinical development strategy, expediate the CMC process and achieve stable and high-quality manufacturing, we believe we are able to continuously develop innovative drugs and achieve our mission.

Our co-founder, Dr. Zhou Pengfei, has over 33 years of extensive experience in the healthcare and pharmaceutical industries, focusing on oncology treatment and innovative drug development. Dr. Zhou worked for a number of leading MNCs, including Schering-Plough Corporation, Crown Bioscience (Beijing) Co., Ltd., and Pfizer-Crown Asian Cancer Research Center. Dr. Zhou also has over eight years of experience serving as a physician. Dr. Zhou has obtained a Ph.D. in molecular immunology from McMaster University, served as a visiting scholar for clinical research at McMaster University School of Medicine, and received post-doctoral training in immunology from Stanford University. Dr. Zhou has filed over 80 patent applications including 15 PCT applications, and has been granted with over 40 issued patents. He has published over 50 research papers. In addition, Dr. Zhou is the leader of the Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) under the 12th Five-Year Plan and the 13th Five-Year Plan. Dr. Zhou also received the honor as a leader leading our Company as one of the “Key Overseas Chinese Entrepreneurial Teams (重點華僑華人創業團隊)” in 2015 recognized by the Overseas Chinese Affairs Office of the State Council (國務院僑務辦公室).

Our outstanding management team has attracted a large number of talents. Our team comprises industry-leading experts with extensive global drug development experience in the pharmaceutical industry. Our department heads and other key technical personnel have served various roles in leading multinational pharmaceutical companies, having complementary experience covering various stages of the entire development lifecycle of drug products, including pre-clinical studies, clinical development, manufacturing and commercialization.

We have developed a cohesive and vibrant corporate culture that inspires and encourages innovation, which we believe helps us to attract, retain and motivate an aspiring team to drive our fast growth. We strive to build a young, yet experienced team with extensive drug development experience, complementary skillsets, and strong synergies in working style. As of the Latest Practicable Date, we have built a team of 122 members, including 99 R&D personnel, 46.5% of which have a master’s degree or higher.

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We believe our strong and dedicated team with its deep industry expertise is the core pillar of our Company and will drive us toward success.

OUR STRATEGIES

To achieve our mission and to further strengthen our market position, we plan to implement the following strategies:

Accelerate the development of our drug candidates

The acceleration of our R&D progress for our drug candidates is our top priority. We will continue to rapidly advance the development of our drug candidates and invest more resources in the following areas: (a) clinical development advancement of our clinical-stage drug candidates to maximize their clinical and commercial potentials; (b) exploration of the potentials of our drug candidates in combination therapy with chemotherapy, radiotherapy and immunotherapy to achieve enhanced efficacy with a favorable safety profile; (c) advancement of the clinical development of M701 for MA to bring M701 to the market in an accelerated pace, and active advancement the clinical development of M701 for other indications, including MPE in multi-center clinical trials; (d) advancement of the clinical development of Y101D, particularly for indications for which no immunotherapy has been approved, including microsatellite stable colorectal cancer, pancreatic cancer, biliary tract cancer, inoperable advanced breast cancer, endometrial cancer, central nervous system tumors, sarcomas (including osteosarcomas), prostate cancer, and neuroendocrine tumors; (e) the further development of our pre-clinical drug candidates, with the aim to advance additional new candidates into clinical development, and (f) the active pursuit of opportunities to develop our drug candidates in major overseas markets.

Continue to expand our pipeline through in-house R&D efforts and collaborations

We believe continuous innovation is critical to our competitiveness and sustainable growth. We will continue to dedicate ourselves to the in-house discovery and development of innovative drug candidates in their respective classes. We endeavor to optimize our drug development process to accelerate the bench-to-bedside translation and improve R&D cost-effectiveness as we maintain our high success rate. We plan to further invest in our core technology platforms, design and generate different antibody structures to bind different targets, and further expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways. We will continue to focus on addressing medical demands in oncology and aging-related ophthalmologic disease areas to enrich our pre-clinical and clinical pipeline to include candidates that pinpoint targets in these areas in order to capture market opportunities. Furthermore, we will continue to design and implement an efficient and cost-conscious clinical development plan to shorten the time-to-market phase of our drug candidates.

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In addition, we will continue to work closely with our existing strategic partners, WIV and CMS Vision, to help advance our collaborative programs. Our dedicated team will also continue to explore additional or expand strategic relationships and opportunities with multinational pharmaceutical companies and domestic companies to derive further value from our platforms and fully exploit the potentials of our pipeline candidates. Given the breadth of opportunities that our technologies and platforms provide, we plan to continue to adopt a flexible approach to pursuing various types of partnerships, including co-development and licensing arrangements. Leveraging our partners’ complementary resources and expertise, we believe we are able to further enrich our pipeline, advance the development of our existing candidates, and maximize the commercial value of our pipeline.

Continue to enhance our manufacturing capabilities

We will continue to enhance our manufacturing capabilities for our BsAbs to leverage our CMC capabilities. We plan to further improve our techniques to ensure the consistent high quality of our drug candidates, and to lower the product costs to effectively compete with other market players.

We plan to further enhance our CMC and manufacturing capabilities through procurement of new machinery, instrument and equipment to improve the efficiency of our production and the quality of our products. This includes: (a) acquiring perfusion systems, fully automatic ultrafiltration systems, small-scale bioreactors, and other equipment to improve antibody expression per unit time and volume of our production line, thereby increasing the efficiency of formulation development sample preparation, (b) procuring automated filling equipment to improve filling efficiency, (c) procuring biomolecular mass spectrometers, high-performance liquid chromatography, capillary electrophoresis, and other analytical quality control equipment to conduct more comprehensive and in-depth characterization of product quality attributes, thereby streamlining product quality control process, and (d) upgrading the corresponding water systems, cold storages to optimize the compatibility of the water system with our current production site.

We will also recruit more professionals in CMC and other technicians. With enhanced manufacturing capabilities, we believe we will be able to deliver our drugs to meet the potential increasing demands for our drugs in the future.

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Continue to build our commercialization capabilities

To continue advancing the potentials of our clinical-stage candidates, we will continue to build our commercialization capabilities. We plan to build our own commercialization team in China with an initial focus on the sales and marketing of our Core Product M701. We intend to market M701 as well as our other drug candidates primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians in the respective therapeutic areas to promote the differentiating clinical aspects of our drug candidates, and to increase the brand awareness and recognition of our Company and our drugs.

We also plan to collaborate with qualified and experienced CSOs to promote and market other drug candidates upon approval in China. Leveraging the CSOs’ experience and sales network in China, we should rapidly achieve wide market coverage of our drugs. We also plan to explore the potential of our drugs in overseas markets, mainly through out-licensing arrangements and/or collaborations with local partners in the future.

Continue to attract, nurture and retain skilled talent

We place a high priority on selecting, nurturing and retaining top talents. Leveraging our position in the development of BsAbs as well as our brand recognition in China, we have been able to, and will continue to, attract skilled talents. We are committed to providing our team with robust career development and learning opportunities, trainings and mentorship from our seasoned team leaders, competitive compensation, and a supportive and dedicated work environment.

To support our continuous growth, we will continue to retain top talent as we enlarge our talent pool. With more of our drug candidates advancing into the clinical stage, in the near term we intend to strengthen our team by attracting talent with extensive experience in clinical development, regulatory affairs and commercialization in China.

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OUR DRUG CANDIDATES

As a biotechnology company, we have developed all of our pipeline candidates in-house by utilizing our proprietary and integrated R&D platforms. We have strategically designed and developed a pipeline of seven clinical-stage drug candidates targeting therapeutic areas with market potentials. The following pipeline chart summarizes the development status of our selected drug candidates:

Candidate ¹	Target	Technology Platform	Type	Regimen	Indication	Pre-clinical	IND	Phase I Phase Ia	Phase Ib	Phase II	Phase III/ Pivotal	Commercial Rights	Current Status/ Upcoming Milestone
★ M701	EpCAMxCD3	YBODY®	BsAb	Mono	Malignant ascites							Global	Phase II commenced in Dec 2021; Expect to initiate Phase III/pivotal trial in Q1 2024 and submit the BLA in Q1 2025
					Malignant pleural effusion							Global	Phase Ib/II commenced in Nov 2022; Expect to initiate Phase III/pivotal trial in Q3 2024 and submit the BLA in Q4 2025
					Solid tumor							Global	Expect to file IND application in Q1 2024 and initiate Phase III in Q2 2024
Y101D	PD-L1×TGF-β	Check-BODY	BsAb	Mono	Solid tumors							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q4 2023
					Pancreatic cancer							Global	Phase Ib/II commenced in Feb 2023; Expect to complete Phase Ib/II in Q3 2024 and initiate Phase III in Q4 2024
					Hepatocellular carcinoma and other advanced solid tumors							Global	Phase Ib/II commenced in Mar 2023; Expect to complete Phase Ib/II in Q2 2025
Y150	CD38×CD3	YBODY®	BsAb	Mono	Small cell lung cancer							Global	Expect to file IND application in Q3 2023; Expect to initiate Phase Ib/II in Q1 2024
					Relapse or refractory multiple myeloma							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q2 2024
					Relapse or refractory multiple myeloma							Global	Expect to file IND application after the completion of the Phase II portion of Phase Ib/II clinical trial of Y150 monotherapy for rMM
Y2019²	SARS CoV-2 RBD homodimer	UVAX®	Vaccine	Mono	COVID-19							Global	Completed Phase Ia
M802	HER2×CD3	YBODY®	BsAb	Mono	HER2-positive solid tumors							Global	Completed Phase I
Y332	VEGF×TGF-β	Nano-YBODY™	BsAb	Mono	Solid tumors							Global	IND application approved in Apr 2023; Expect to initiate Phase I in Q3 2023
Y400	VEGF×ANG2	Nano-YBODY™	BsAb	Mono	wAMD, DME and other ocular neovascularization related diseases							Global ³ CMS Vision	IND application approved in Apr 2023

★ **Core Product**  **Clinical Stage**  **Pre-clinical Stage**

Notes:

- (1) Except for Y2019, all of our drug candidates are in-house developed.
- (2) Specific combination drug(s) of the trial will be decided prior to the commencement of the trial.
- (3) We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluates the safety and tolerability of Y2019 in healthy adults, and obtained ethical committee approval for the Phase IIa clinical trial. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.
- (4) We have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China. For more details, please refer to the paragraphs headed “– Collaboration Agreements – Collaboration with CMS Vision” in this section.
- (5) Some of our drug candidates are not included in the pipeline chart as they are at the early preliminary stage.

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Abbreviations: Mono refers to monotherapy; Combo refers combination therapy; EpCAM refers to epithelial cell adhesion molecule; CD3 refers to cluster of differentiation 3; PD-L1 refers to programmed death ligand 1; TGF- β refers to transforming growth factor- β ; CD38 refers to cluster of differentiation 38; COVID-19 refers to coronavirus disease 2019; RBD refers to recombinant receptor-binding domain; HER2 refers to human epidermal growth factor receptor 2; VEGF refers to vascular endothelial growth factor; ANG2 refers to angiopoietin-2; wAMD refers to wet age-related macular degeneration; DME refers to diabetic macular edema.

M701 (EpCAM $\times$ CD3 BsAb) – Our Core Product

M701 is a recombinant BsAb that targets human epithelial cell adhesion molecule (EpCAM)-expressing cancer cells and human cluster of differentiation 3 (CD3)-expressing T cells. M701 is designed to kill tumor cells by different mechanisms of action such as T cell activation, antibody-dependent cell-mediated cytotoxicity (ADCC), and complement-dependent cytotoxicity (CDC). According to relevant research paper published on *Frontiers in Immunology*, EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens, and thus is an attractive target for antibody therapy of oncology, particularly carcinomas of various origins. We are developing M701 for the treatment of MA and MPE.

According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. We completed a Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China in January 2022. We are currently conducting a Phase II clinical trial of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MA in the first quarter of 2024. The expected BLA submission time will be in the first quarter of 2025 and the expected commercial launch time will be in the fourth quarter of 2025. In addition, we commenced a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MPE in the third quarter of 2024. The expected BLA submission time will be in the fourth quarter of 2025 and the expected commercial launch time will be in the second quarter of 2026. Furthermore, we expect to commence a Phase I/II clinical trial for treatment of solid tumor in the second quarter of 2024.

We are developing M701 in-house and own its global IP and commercial rights. As of the Latest Practicable Date, we owned two PCT applications in relation to M701, including one PCT applications that are generally applicable to our YBODY[®] molecules, including M701 and M802, and one PCT application specifically relating to M701. As of the same date, one PCT application had entered into national phase in major markets, including five granted patents in China, Canada, the U.S. and Japan, and one pending patent applications in China; and the other PCT application was published.

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EpCAM is a type I transmembrane glycoprotein. EpCAM plays a role in epithelial carcinogenesis and is involved in various biological functions, such as cell cycle progression, cell proliferation, differentiation, migration, and immune evasion. In normal tissues, EpCAM is only expressed baso-laterally and is shielded by tight junctions that limit its accessibility. However, EpCAM is also expressed on the whole cell surface in tumor cells, and thus is more easily available for binding.

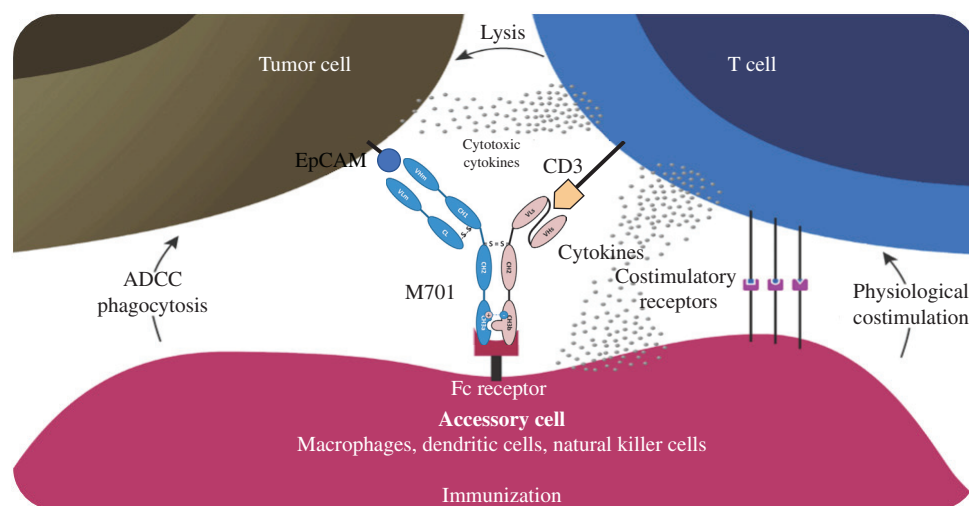
CD3 is expressed on all human T cells. Together with the T cell antigen recognition receptor (TCR), CD3 forms a TCR/CD3 complex and mediates the intracellular transduction of activation signals produced by TCR to activate T cells and perform effector functions.

M701 binds to both tumor cells and T cells by using EpCAM as the target on tumor cells and CD3 as the target on T cells, respectively. M701 contains the constant region of human IgG1 as the structural framework, whose Fc fragment can trigger ADCC and CDC. It also improves the tumor-targeting ability of T cells and their immune killing effect on tumor cells. M701 binds to EpCAM and blocks the downstream signal of EpCAM to inhibit tumor growth. By binding to T cell surface antigen CD3, M701 promotes T cell activation and proliferation and the release of cytokines, such as TNF α , IFN- γ , perforin and granzyme B to kill tumor cells. In addition, M701 shows cytotoxicity against tumor cells through ADCC and CDC.

M701, as an asymmetrical BsAb that leverages the technology of YBODY[®] platform, features moderate affinity to human immune cells, which reduces non-specific activation of T cells and the toxicity of cytokine release syndrome, an adverse event commonly seen in some CD3-based antibodies. In a preclinical study involving *in vivo* experiments, it was found that reducing the CD3-arm binding affinity of bispecific antibodies (bsAbs) still allows for a potent antitumor response while limiting systemic cytokine levels (Scientific Reports volume 11, Article number: 14397 (2021)). Another preclinical study demonstrated that compared to bsAbs with high CD3 affinity (<1 nM), the HER2xCD3 bsAb with low CD3 affinity (50 nM) could avoid being captured by circulating T cells, decrease its distribution in tissues rich in T cells such as spleen and lymph nodes, and be more enriched in tumor tissues with high HER2 expression, thereby reducing off-target toxicity (Mol Cancer Ther; 17(4) April 2018). Moreover, it was revealed in the Multi-Disciplinary Review and Evaluation for BLA applications submitted to the FDA that the CD3 affinities of the bsAbs teclistamab and mosunetuzumab were 28.03 nM and 40 nM, respectively, which indicates a moderated CD3 affinity. These findings clearly indicate that a lower CD3 affinity of CD3 bsAbs does not impair efficacy but can significantly improve safety by reducing cytokine release and off-target toxicity.

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The following diagram illustrates the mechanism of action of M701:



Source: Company data

Market Opportunities and Competition

EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens. Due to its frequent overexpression in carcinomas, EpCAM has been widely studied as a target for cancer diagnostics and treatment.

EpCAM-positive tumors

EpCAM overexpression is widely observed in many carcinomas. According to relevant research papers, such as Went, P., et al. “Frequent high-level expression of the immunotherapeutic target EpCAM in colon, stomach, prostate and lung cancers.” British journal of cancer, high EpCAM expression is observed in approximately 90% of gastric cancer and colorectal cancer, approximately 80% of prostate cancer, approximately 60% of lung cancer, over 50% of ovarian cancer, approximately 50% of breast cancer and kidney cancer, and approximately 10% to 15% of hepatocellular carcinoma (HCC).

MA and MPE

MA is the accumulation of fluid in the peritoneal cavity resulting from the growth of primary or metastatic malignant neoplasms in the peritoneum. The most common etiologies for MA are ovarian cancer, HCC, pancreatic cancer, gastric cancer, esophageal cancer, colorectal cancer and breast cancer. The incidence of MA in China has grown from approximately 533.3 thousand in 2017 to approximately 591.8 thousand in 2021, representing a CAGR of 2.6%. It is expected that the prevalence will increase to approximately 654.0 thousand in 2025 and 729.8 thousand in 2030, at a CAGR of 2.5% and 2.2% from 2021 to 2025 and from 2025 to 2030, respectively.

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MA often leads to abdominal pain and swelling, dyspnea, nausea, vomiting, malnutrition and anorexia. The causes of MA are independent of the origin of the primary tumor. Tumor-secreted factors lead to tumor neovascularization and increased capillary permeability, resulting in increased plasma inflow into the peritoneal cavity. Tumor cells obstruct lymphatic drainage, leading to decreased fluid efflux from the peritoneal cavity.

MPE is the collection of fluid in the pleural cavity resulting from malignant disease. Malignant pleural effusions often contain free floating malignant cells. The most common etiologies for MPE are lung cancer, breast cancer, lymphoma, ovarian cancer and gastric cancer. MPE is observed on approximately 45% of lung cancer patients, 2% to 11% of breast cancer patients, 41.6% of lymphoblastic lymphoma patients, and 33% of ovarian cancer patients. The incidence of MPE in China has grown from approximately 536.4 thousand in 2017 to approximately 605.6 thousand in 2021, representing a CAGR of 3.1%. It is expected that the prevalence will increase to approximately 683.1 thousand in 2025 and 779.1 thousand in 2030, at a CAGR of 3.1% and 2.7% from 2021 to 2025 and from 2025 to 2030, respectively.

Current treatment and limitations

Current treatment options for MA and MPE primarily are medical therapies, including paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration. Among these treatments, paracentesis and diuretics are conventional management methods, hyperthermic intraperitoneal chemotherapy is a kind of local therapy. Given that MA and MPE are complications of cancer, the current treatment paradigm for MA and MPE do not distinguish between first-line/second-line/late-line therapies. Therapeutic paracentesis is the only physical treatment method currently recommended by clinical guidelines for controlling MA/MPE. For details, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM × CD3 Targeted BsAb – Treatment Paradigm for MA and MPE in China” in this document. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis.

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Competitive landscape

According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins, as illustrated below.

Global Pipeline							
Product	Developer	Highest Clinical Stage	Indication	Region	Drug Type	Target	First Posted Date ⁽¹⁾
Catumaxomab	TRION Pharma GmbH and Neovii Biotech GmbH	Approved in 2009, withdrew from market in 2017, applied for renewal of the marketing authorization in 2022	Cancer, Neoplasms, Carcinoma, MA	France, Germany, Italy, Spain	BsAb	EpCAM, CD3	—
ENDOSTAR™	Jiangsu Simcere Pharmaceutical Co., Ltd.	Phase III	MPE, Malignant Peritoneal Effusion	China	Other Protein	Endostatin	2021/05/27
M701	the Company	Phase II	MA	China	BsAb	EpCAM, CD3	2021/07/23
M701	the Company	Phase Ib/II	MPE	China	BsAb	EpCAM, CD3	2022/08/08
GAIA-102	Gaia BioMedicine Inc; Kyushu University Hospital	Phase II	MA, Stomach Neoplasms, Pancreatic Neoplasms, Carcinoma, NSCLC	Japan	Cell Therapy	—	2021/11/19
RSO-021	RS Oncology LLC	Phase I/II	MPE, Malignant Pleural Mesothelioma, Mesothelioma, Solid Tumor	United Kingdom	Polypeptide	—	2022/02/07
VAK	Wuhan Binhui Biotechnology Co., Ltd.	Phase I	MPE, Malignant Peritoneal Effusion	China	Cell Therapy	—	2022/09/29
IFN-γ and CIK cells, Tem cells or CAR-T cells	Affiliated Hospital of Jiangnan University	Phase I	MPE	China	Cell Therapy	—	2022/03/07

Source: NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

Among them, catumaxomab (developed by TRION Pharma GmbH and Neovii Biotech GmbH) is the world’s first marketed BsAb and has two targets identical to M701 which was approved in 2009 for the treatment of MA. Upon the initial commercial launch of catumaxomab in 2009, based on public information, the medical community’s understanding of immunotherapy and BsAb was not fully developed, which limited the comprehension of the mechanism of actions of catumaxomab, resulting in a relatively cautious approach towards the clinical application of the drug. Moreover, based on public information, the developers of catumaxomab fell short in formulating a market-oriented marketing strategy for catumaxomab, which led to poor sales performance after its launch and its subsequent withdrawal from the market in 2017. Catumaxomab was marketed in Europe only and the withdrawal of catumaxomab only impacted the Europe market. The withdrawal of catumaxomab was primarily due to timing and sales strategy instead of safety and efficacy concerns. Despite of

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that, as the world’s first BsAb drug, the withdrawal of catumaxomab did impact the overall perception of BsAbs within the medical community for a period of time. However, this perception has gradually improved with the increase in marketed BsAb drugs and their clinical use. Catumaxomab demonstrated manageable safety and encouraging efficacy during its clinical use. Therefore, the developers of catumaxomab applied for the renewal of the EMA marketing authorization of the drug for the treatment of MA in August 2022, which is currently under review.

In addition, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in a Phase III clinical trial for stomach neoplasms, advanced gastric carcinoma with peritoneal metastasis, and a Phase I/II clinical trial for non-muscle-invasive bladder cancer in China. Based on publicly available information, LintonPharm is developing catumaxomab in collaboration with LINDIS Biotech, a research partner of TRION Pharma GmbH. LINDIS Biotech is also evaluating catumaxomab in a Phase I clinical trial for urinary bladder neoplasms in German. Catumaxomab is expected to be available in China and Europe upon successful commercialization.

Moreover, peer products targeting identical molecular targets as M701 are under clinical development. According to public information, the following table sets forth BsAb pipelines targeting EpCAM and CD3 and mAb, antibody fusion protein and CAR-T pipelines targeting EpCAM currently under clinical development globally. As of the Latest Practicable Date, these competitors have not developed their EpCAM × CD3 drug candidates for the treatment of MA/MPE, however we cannot guarantee that these companies will not expand into our target market.

Product	Developer	Drug Type	Target	Highest Clinical Phase	Region	First Posted Date	Indication
BA3182	BioAtla	BsAb	EpCAM, CD3	I	United States	4/1/2023	Advanced Adenocarcinoma
M701	Our Company	BsAb	EpCAM, CD3	I/II	China Mainland	9/30/2022	MA, MPE, Solid Tumor
Catumaxomab	LintonPharm Co., Ltd.	BsAb	EpCAM, CD3	III	China Mainland	10/6/2020	Stomach Neoplasms Advanced Gastric Carcinoma With Peritoneal Metastasis, Non-Muscle-Invasive Bladder Cancer
Catumaxomab	LINDIS Biotech	BsAb	EpCAM, CD3	I	German	7/7/2020	Urinary Bladder Neoplasms
AM-928	AcadeMab Biomedical	mAb	EpCAM	I	United States	1/7/2023	Solid Tumors
VB4-845	Qilu Pharmaceutical Co., Ltd.	Antibody fusion protein	EpCAM	III	China Mainland	4/13/2021	Non-Muscle Invasive Bladder Cancer
TM4SF1- positive chimeric antigen receptor T-cell therapy, EpCAM- positive chimeric antigen receptor T-cell therapy	Shanghai Biomedunion Biotechnology Co., Ltd.	CAR-T	EpCAM, TM4SF1	NA	China Mainland	10/29/2019	Solid Tumors

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Among them, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in clinical trials for advanced gastric cancer and for non-muscle invasive bladder cancer in China. Based on publicly available information, LintonPharm is developing catumaxomab in collaboration with LINDIS Biotech, a research partner of TRION Pharma GmbH. In the bladder cancer Phase I clinical trial sponsored by LintonPharm Co., Ltd., 6 participants received catumaxomab achieved a complete response, with the duration of response lasting 9.5 months. In addition to the above

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pipelines, Amgen Inc. commenced a multicenter Phase I clinical trial of solitomab, a bispecific EpCAM×CD3 T-cell engager BsAb in patients with refractory solid tumors in 2008. According to public information, Amgen Inc. has removed solitomab from its pipeline update since 2015, indicating that it may have suspended the clinical development plan for the drug candidate. We have not learned from public information that solitomab has safety or effectiveness issues. Amgen’s suspension of this pipeline may be due to strategic considerations.

Limitations and imminent risks on the market potential of M701

We face the following limitations and imminent risks on the market potential of M701:

- MA and MPE, the intended indications of M701, are complications of the tumor. The continual refinement of early tumor detection methods, preventive measures, non-drug treatment options, along with the relentless innovation in tumor treatment methodologies, will reduce tumor prevalence and improve early-stage tumor cure rates, subsequently decreases the occurrence of MA and MPE as complications of the tumor.
- Other therapies for primary and metastatic cancers, including but not limited to chemotherapy, targeted therapies, and immunotherapies, while not directly targeting MA and MPE, can help control these complications. Compared to such systematic treatments that have a curative effect on cancer, M701 is primarily used to improve symptoms and complications of cancer, which might be less attractive to doctors and patients. Approximately 10% of patients with mild symptoms of MA and MPE only need these cancer systematic therapies to control their MA and MPE. These therapies for cancer thereby indirectly limit the market size for M701.
- Current medical treatment methods for MA and MPE, including primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature. Among these current treatment options for MA and MPE, therapeutic paracentesis is recommended by clinical guidelines for controlling MA/MPE which can alleviate symptoms for one to two weeks. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis. However, this method will also be more expensive and may not be affordable by some patients.
- The market size for MA and MPE is relatively limited when compared to the oncology drug market. Comparing with the rapid growth of the oncology drug market in China, the overall growth rate for the China market size of MPE and MA therapies is comparatively stable, which could further limit the market potential of M701.

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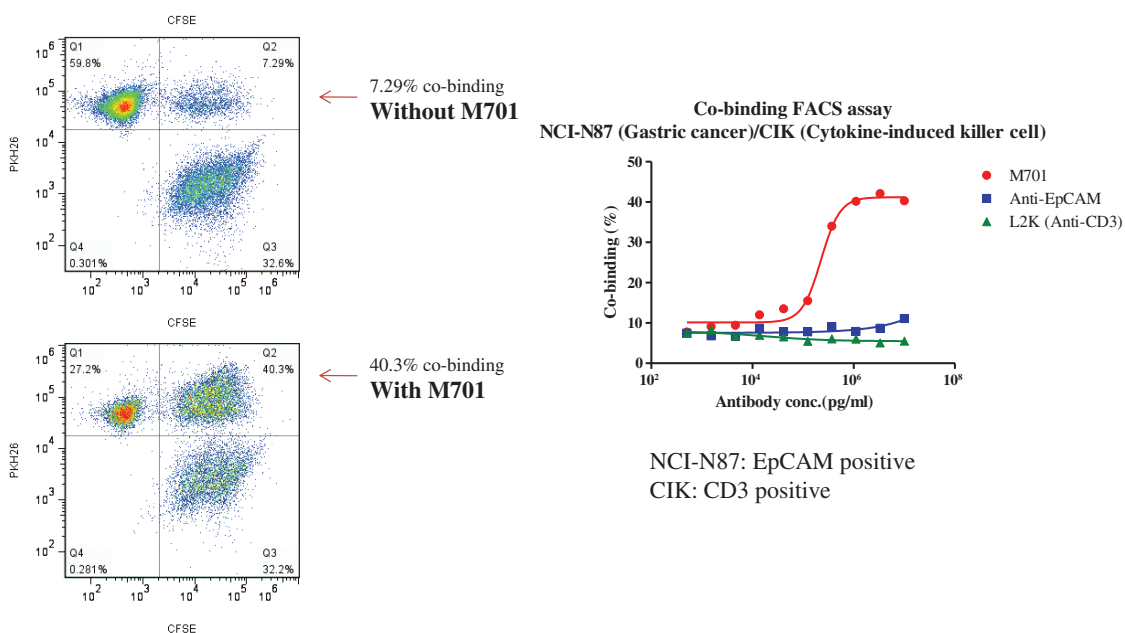
Competitive Advantages of M701

Optimized structure designed to bind both EpCAM and CD3

M701 is designed based on the molecular structure YBODY[®] and is mainly comprised of anti-EpCAM heavy chain, anti-EpCAM light chain, and anti-CD3 single chain. M701 can specifically bind to EpCAM, an antigen highly expressed in tumors on the one hand, and, on the other hand, to human T cell surface antigen CD3. EpCAM is an antigen highly expressed in tumors, and lowly expressed in normal human epithelial tissues. Therefore, M701 causes a very limited biological effect when binding to EpCAM in normal cells. CD3 is a surface antigen on normal human T cells that are distributed almost all over the body. M701 is able to quickly bind to human T cells' surface antigen CD3 in humans, resulting in a rapid decline of plasma concentration of free M701; T cell activations induce various biological effects, such as T cell proliferation and cytokine release, which causes systemic and transient cytokine release syndrome.

M701 has demonstrated high affinity and specificity to EpCAM in pre-clinical studies. The proprietary structure of M701 enables it to bind EpCAM with high affinity and CD3 with moderate affinity. Furthermore, M701 mediates the linkage of CD3-positive cells with EpCAM-positive tumor cells, but not with EpCAM-negative tumor cells, indicating that M701-mediated linkage is EpCAM-dependent and that M701 can redirect the CD3-positive immune cells to the targeted EpCAM-positive tumor cells, as shown below:

Compared to the control mAbs, M701 mediates association between tumor cells and immune cells



Source: Company data

Abbreviation: FACS refers to fluorescence activated cell sorter.

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Anti-EpCAM, an mAb against EpCAM, and L2K, an mAb against CD3, and M701 were assessed in the above co-binding FACS assay. Among the three molecules, only M701 is able to mediate the interaction between tumor cells NCI-N87 and immune cells CIK, with a maximum co-binding percentage of 42.1%. Neither of the other two mAbs are able to mediate the interaction between the tumor cells and immune cells. The table below sets forth the results of the above co-binding FACS assay.

Sample	Co-binding (%)	EC50 (ng/mL)
M701	42.1	226.8
Anti-EpCAM	11.1	—
L2K	9.5	—

Source: Company data

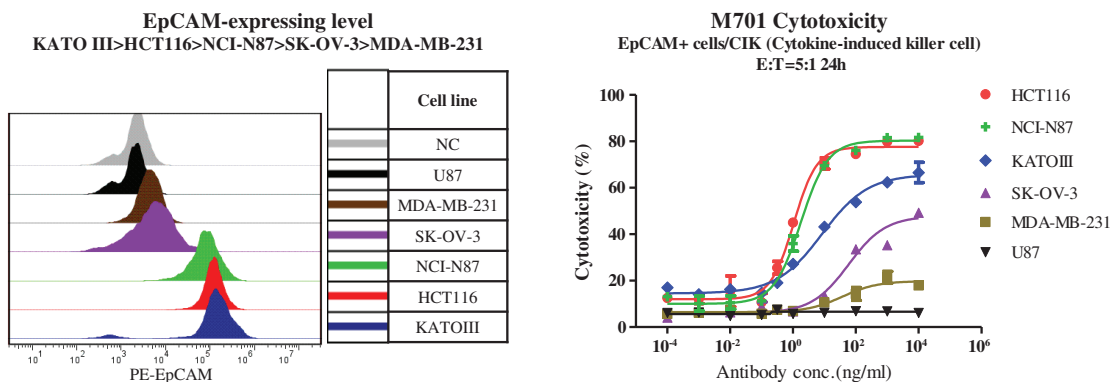
Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

Encouraging ascites controlling capability activity

M701 has demonstrated a strong killing activity to all tested EpCAM-positive cells in a dose-dependent manner *in vitro* and *in vivo* studies.

In the *in vitro* pharmacodynamic studies, EpCAM-positive cells, including HCT116 (a colorectal cancer cell line), OVCAR3 (an ovarian cancer cell line), and KATOIII (a gastric cancer cell line), were used as the target cells, and the peripheral blood mononuclear cells (PBMCs), cytokine-induced killer cells (CIKs), or T cells were used as the effector cells. A primary glioblastoma cell line U87 was used as EpCAM-negative controls. M701-mediated killing activity of effector cells on the tumor cells was examined both *in vitro* and *in vivo*. *In vitro* studies have shown that M701 demonstrates a strong killing activity to all tested EpCAM-positive cells in a dose-dependent manner. *In vitro* mechanism studies have shown that M701 mediates the linkage of EpCAM-positive cancer cells and CD3-positive T cells, mediates ADCC and CDC activities on some cancer cells, and induces cancer cell apoptosis. Most importantly, M701 activates T cells, thereby largely increasing the expression levels of activation markers on T cells and inducing the secretion of cytokines, including IFN- γ , TNF α , perforin and granzymes, which lead to the killing of cancer cells.

Cytotoxicity of M701 to various cancer cells with different EpCAM expression level



Source: Company data

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The table below sets forth the maximum lysis percentage and the EC50 value of M701 on different tumor cells with descending levels of EpCAM expression, in the presence of CIKs. As shown below, EpCAM over-expressing cell lines HCT116 (colon cancer) NCI-N87 (gastric cancer) and KATOIII (gastric cancer) were significantly more sensitive to M701-mediated killing (as demonstrated by the low-level of EC50) than the low-level expressing cell line SK-OV-3 (ovarian cancer), MDA-MB-231 (breast cancer) and U87 (glioma), as demonstrated by high-level of EC50.

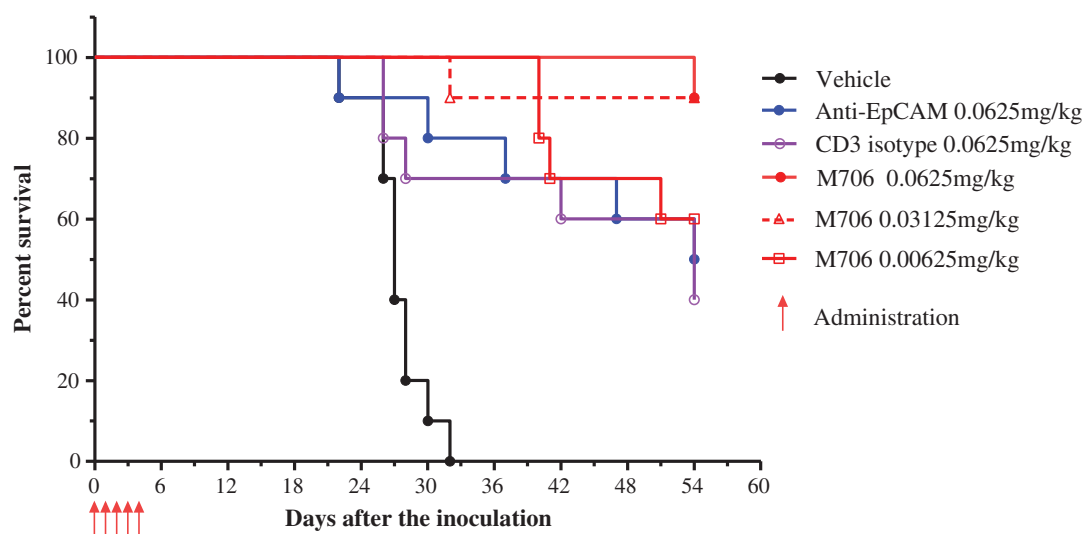
EpCAM expressed cancer cell	Maximum lysis (%)	EC50 (ng/ml)
KATOIII (gastric cancer)	66	8.5
HCT116 (colon cancer)	78	1.1
NCI-N87 (gastric cancer)	80	1.8
SK-OV-3 (ovarian cancer)	48	58.7
MDA-MB-231 (breast cancer)	20	37.8
U87 (glioblastoma, negative control)	6	—

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

As shown below, the survival rate of mice treated with anti-EpCAM mAb after 54 days post-inoculation was 50%, whereas the survival rate of mice treated with CD3 isotype was 40%. In contrast, the survival rate of mice treated with the same dosage (0.0625 mg/kg) of M706 (EpCAM × murine CD3 BsAb, the mouse surrogate of M701) was 90%, and the survival rate of mice treated with a lower dose of 0.03125 mg/kg of M706 was also 90%. In addition, the survival rate of mice treated with the lowest dose of 0.00625 mg/kg of M706 was 60%. These results indicate that the efficacy of M706 is dose-dependent and significantly superior to the mAb control group.

**In the CT26-hEpCAM ascites tumor model
The efficacy of the surrogate M706 was significant and dose-dependent**



Source: Company data

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The table below shows the survival rates of mice treated with anti-EpCAM mAb, CD3 isotype and different doses of M706 at 54 days post-inoculation in the CT2-hEpCAM ascites tumor model.

Sample	Dosage(mg/kg)	Survival rates of mice at 54 days post-inoculation
Vehicle	0	0
anti-EpCAM mAb	0.0625	50%
CD3 isotype	0.0625	40%
M706	0.0625	90%
M706	0.03125	90%
M706	0.00625	60%

Source: Company data

The advantages of the structure design of M701 have also translated into clinical benefits. Among 18 patients who have completed the core treatment period, three patients reached complete response (CR), which means the complete disappearance of ascites for at least four weeks, and eight patients reached partial response (PR), which means at least a 50% reduction in the volume of ascites for at least four weeks. Therefore, the clinical trial results showed an ORR of approximately 61.1% (11/18). Furthermore, among the 18 patients who have received at least four times of treatment during the dose-escalation phase, the median overall survival (mOS) reached 151.5 days in this clinical trial.

Manageable safety profile

Data obtained from this Phase I clinical trial for the treatment of MA shows that M701 monotherapy is well tolerated and safe up to 400µg. Only two subjects with DLT were observed at cohort 7 (with an initial dose level at 100µg and a maintenance dose level at 600µg). Therefore, MTD was determined at the dose level of cohort 6 (with an initial dose level at 50µg and a maintenance dose level at 400µg). 15 out of 35 enrolled subjects did not experience any TRAE, and only 5 patients experienced Grade 3 TRAEs during the trial, indicating the manageable safety profile of M701. For more details, please refer to the paragraphs headed “– M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results” in this section.

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Leading development progress in China

EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens. As a result, EpCAM becomes an attractive target for antibody therapy of oncology, particularly carcinomas of various origins. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. Currently, patients with MA and/or MPE have limited treatment options and poor prognoses. Therefore, we believe M701 has potential to address the medical needs.

Summary of Clinical Trial Results

We received an IND approval from the NMPA for the Phase I, II and III clinical trials of M701 on February 12, 2018. We commenced a Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China in January 2019, and completed this clinical trial in January 2022. We are currently conducting a Phase II clinical trial of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China. As of March 31, 2023, a total of 53 subjects were enrolled in this Phase II clinical trial.

Completed Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China.

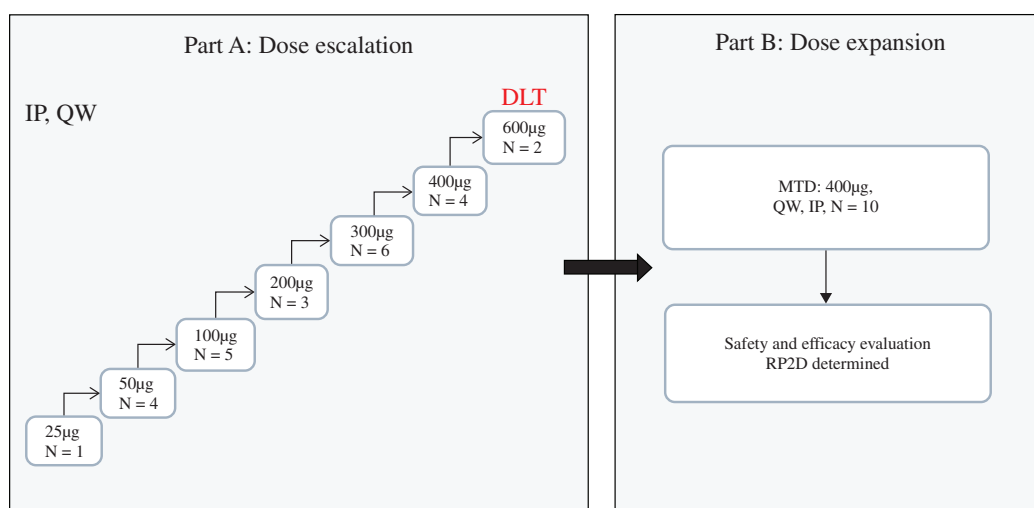
Trial design

This is a Phase I, multicenter, open-label, multiple-ascending dose study of M701 monotherapy. This trial has enrolled a total of 35 subjects who have failed the standard treatment and require therapeutic paracentesis. Subjects who meet the inclusion criterion of “failed standard treatment and require therapeutic paracentesis” are individuals who have completed at least one systemic standard treatment regimen but failed to control the generation and accumulation of ascites. These individuals may present with symptoms such as abdominal pain, distension, poor appetite and intestinal obstruction. A clinical physician has determined that these symptoms require the use of paracentesis for relief. Additionally, the investigator must determine that the patient does not have an effective systemic treatment option available, or that the patient has refused systemic treatment, or that the patient requires immediate paracentesis to alleviate symptoms.

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Patients are scheduled to undergo a 2-week screening period and a 4-week core treatment period (treatment received once weekly for 4 weeks). Following completion of the core treatment period, patients who demonstrate good tolerance and do not exhibit progression of ascites or systemic tumor as evaluated by imaging, and who also express willingness may continue to enter into the extended treatment period (treatment received once weekly for 4 weeks) until disease progression or toxicity intolerance.

In the dose escalation phase, 25 subjects received M701 intraperitoneal injections once weekly across seven cohorts with 1, 4, 5, 3, 6, 4 and 2 subjects enrolled and received maintenance dose level at 25 µg, 50 µg, 100 µg, 200 µg, 300 µg, 400 µg and 600 µg, respectively, in the corresponding cohort. In the dose expansion phase, ten subjects received M701 intraperitoneal injections once weekly with dose level at 400 µg where the safety and preliminary efficacy of M701 were evaluated and RP2D were determined. Further details are illustrated in the diagram below.



Source: Company data

Abbreviations: IP refers to intraperitoneal injections; QW refers to once weekly; DLT refers to dose-limiting toxicity; MTD refers to maximum tolerable dose; RP2D refers to recommended Phase II dose.

The primary objectives of this Phase I clinical trial were to evaluate the safety and tolerability of M701, while the secondary objectives were to evaluate PK, PD, and immunogenicity and to preliminarily assess the efficacy in treating ascites and tumors in patients. The primary endpoints include DLT, MTD, and incidence of AEs, among others. The secondary endpoints include PK, PD, immunogenicity and preliminary efficacy.

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Trial status

We commenced this trial in January 2019 and completed it in January 2022 with a total of 35 subjects enrolled. The following table sets forth the number of subjects enrolled in this Phase I clinical trial of M701 by cancer type.

Cancer types	Number of subjects enrolled for the Phase I clinical trial
Ovarian cancer	14
Colorectal cancer	7
Gastric cancer	6
Primary peritoneal carcinoma	4
Other types of cancer	4
Total	35

Safety results

Data obtained from this trial shows that M701 monotherapy is well-tolerated and safe up to 400µg. Only two subjects with DLT were observed at cohort 7 (with an initial dose level at 100µg and a maintenance dose level at 600µg). Therefore, MTD was determined at the dose level of cohort 6 (with an initial dose level at 50µg and a maintenance dose level at 400µg). DLT, or dose-limiting toxicity, refers to the occurrence of Grade 3 or above AEs as specified in the clinical trial protocol, which is considered to be possibly or definitely related to the medication during the dose escalation phase of a Phase I clinical trial. Typically, when DLT occurs, the study investigators will expand the cohort of participants at that dose level to further evaluate the toxicity risk or determine that the dose is not tolerable. MTD, or maximum tolerated dose, refers to the highest dose cohort in which no DLT are observed in a Phase I clinical trial. It is the highest dose of the medication that can be tolerated by the study participants. The MTD observed in this trial (at cohort 6 with a maintenance dose level at 400µg) is considered to be manageable and meets the expectations of the researchers vis-à-vis accepted medical standards adopted as industry norm.

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The following table sets forth the number of patients experiencing TRAEs by different cohorts. 15 out of 35 enrolled subjects did not experience any TRAE, and only 5 patients experienced 6 Grade 3 TRAEs during the trial, indicating the manageable safety profile of M701.

	Grade 1 TRAEs	Grade 2 TRAEs	Grade 3 TRAEs
Cohort 1	1	0	0
Cohort 2	1	1	2
Cohort 3	3	1	0
Cohort 4	1	0	0
Cohort 5	2	1	1
Cohort 6	8	5	1
Cohort 7	1	1	2
Total	17	9	6

Source: Company data

Note: Each patient in the trial may experience multiple incidences of TRAEs in different grades. For example, a patient experienced both Grade 1 and Grade 2 TRAEs will be counted toward the number of Grade 1 and Grade 2 TRAEs at the same time. Therefore, although only 20 patients experienced TRAEs in this trial, the number of patients experiencing TRAEs is presented as 31 in this table.

The following table presents the symptoms of TRAEs by different cohorts.

	Symptoms
Grade 1 TRAEs	Hypoalbuminemia, decrease in platelet count, decrease in white blood cell count, anemia, hypokalemia, lactic acidosis, fever, abdominal pain, increase in neutrophil, anorexia, fatigue, etc.
Grade 2 TRAEs	Hypochloremia, elevation of alanine transaminase, anemia, chest tightness, tachycardia, abdominal distention, constipation, abdominal pain, cytokine release syndrome, etc.
Grade 3 TRAEs	Elevation of aspartate transaminase, hypertension, anemia, intestinal obstruction and general fatigue.

Source: Company data

The symptoms for Grade 3 TRAEs in cohorts 2, 5 and 6 are elevation of aspartate transaminase, hypertension and anemia. None of these symptoms resulted in a patient withdrawal in this trial. However, two patients in cohort 7 experienced general fatigue and intestinal obstruction, and subsequently withdrew from this trial. Therefore, the Cohort 7 dose level (with an initial dose level at 100µg and a maintenance dose level at 600µg) was

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determined as the DLT dose level. As a result, MTD was determined at the dose level of cohort 6 (with an initial dose level at 50µg and a maintenance dose level at 400µg). We have reported to the CDE on the TRAEs occurred in this trial and CDE did not raise any concern in this regard.

Efficacy results

The data obtained from this trial shows preliminary clinical efficacy of M701 monotherapy. Of the 35 enrolled patients, 18 of them have completed the 4-week core treatment period in the escalation phase, with treatment received once weekly for 4 weeks. Reasons for patients not completing the 4-week core treatment period in the escalation phase primarily is patient withdrawal, and secondarily are disease progression, AEs, and recommendation from the investigators. Failure for certain subjects to complete treatment in a clinical trial is common in the industry. Among these 18 patients, three patients reached CR, which means complete disappearance of ascites for at least four weeks based on CT evaluation, and eight patients reached PR, which means at least a 50% reduction in the volume of ascites for at least four weeks based on CT evaluation. The use of CT evaluation for evaluating M701's preliminary efficacy in treating MA is in line with WHO guidelines. There, the clinical trial results show an ORR of approximately 61.1% (11/18). The ORR is a measure of the proportion of study participants who show a complete or partial remission (CR or PR) of ascites, as evaluated by imaging or other objective methods, according to the imaging criteria specified in the clinical trial protocol. ORR is a specific numerical value and do not necessarily indicate the efficacy of a treatment on its own. Rather, it must be compared to the corresponding values of current standard treatment options or to the expectations of the researchers or reviewers. If the results show a statistically significant increase, the new therapy is considered superior. If the results are not statistically significant, the new therapy is considered similar in efficacy to the current standard treatment but may be approved due to its advantages in terms of safety or convenience. In the case of M701, a treatment therapy for MA, there is currently no standard treatment option to be compared with. Thus, evaluation of its ORR vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. M701's ORR data surpass the researchers' expectations formed based on historical data from other treatments for MA in the literature including Bevacizumab, cisplatin chemotherapy, cisplatin chemotherapy in combination with Endostar™, and Recombinant Tumor Necrosis Factor (rTNF) treatment and their own clinical treatment experience, indicating the preliminary efficacy for M701.

The main purpose of the Phase I study of M701 is to evaluate the safety profile of M701. The preliminary claim of efficacy of M701 based on the Phase I data only relies on a limited number of patients and may not be indicative of future clinical results.

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The following table sets forth the ORR results by different cohorts.

Cohort	Subjects completing the 4-week core treatment period	PR	CR	ORR
Cohort 1	1	0	0	0
Cohort 2	3	2	0	66.70%
Cohort 3	3	2	1	100%
Cohort 4	3	2	0	66.70%
Cohort 5	4	0	2	50%
Cohort 6	4	2	0	50%
Total	18	8	3	61.10%

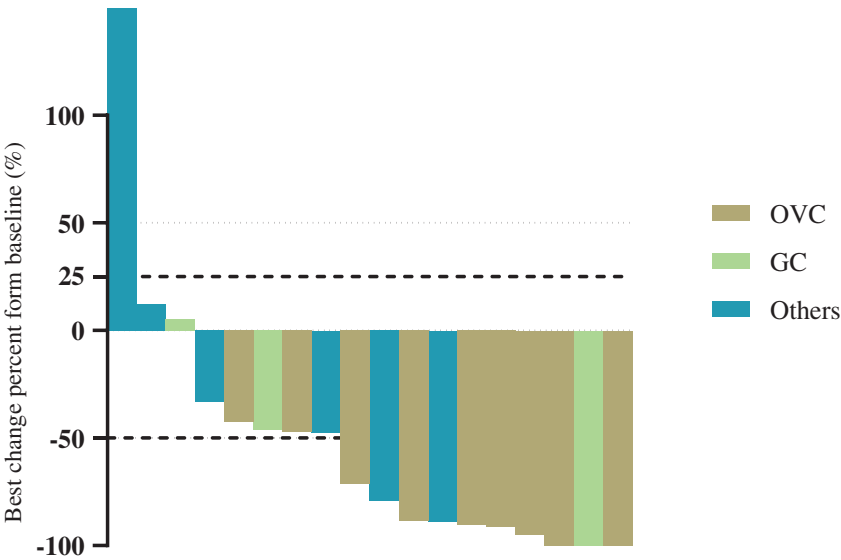
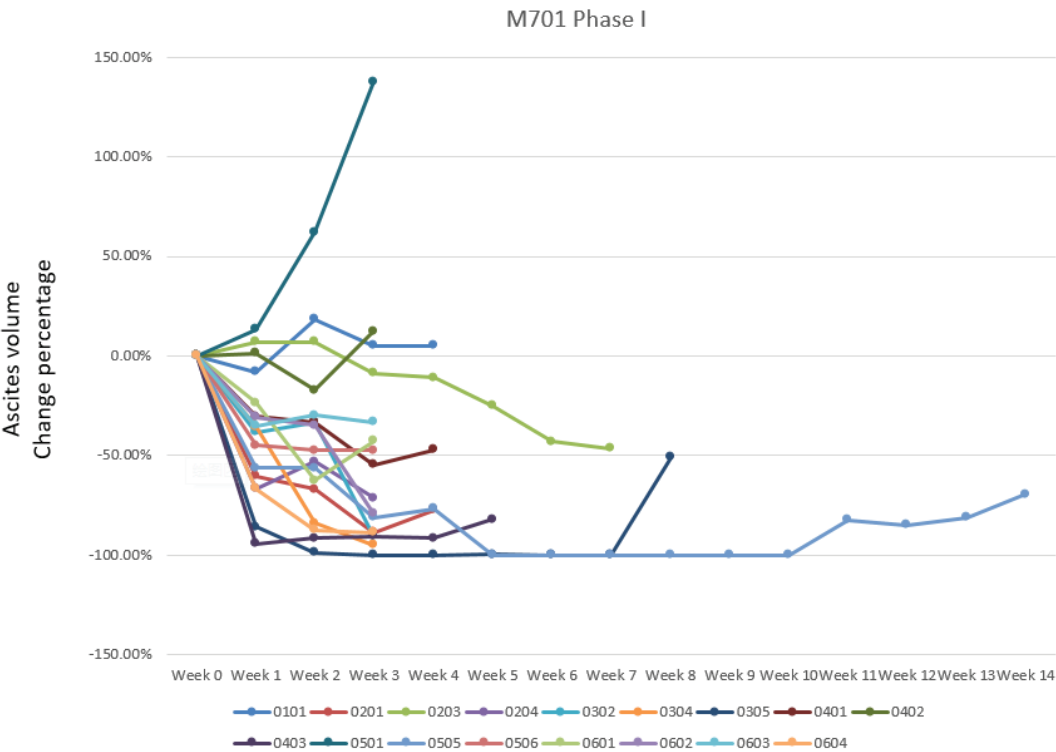
Source: Company data

Abbreviations: PR refers to partial response; CR refers to complete response; ORR refers to objective response rate

Out of 18 patients who have completed the 4-week core treatment period in the escalation phase, 9 patients entered the extended treatment period. The main reason for certain patients not entering the extended treatment period was tumor progression, followed by AEs and patient withdrawal. Patients who enter the extended treatment period will continue to receive M701 treatment without a fixed completion date. Throughout the course of the trial, many patients experienced cancer progression or deterioration in their overall health, necessitating the resumption of systematic treatment for the tumor, rendering them unable to complete the trial or move into the extended treatment period according to the trial protocol.

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The following two diagrams show the efficacy results of patients who have completed the 4-week core treatment period in the escalation phase:



Ascites BOR

Source: Company data

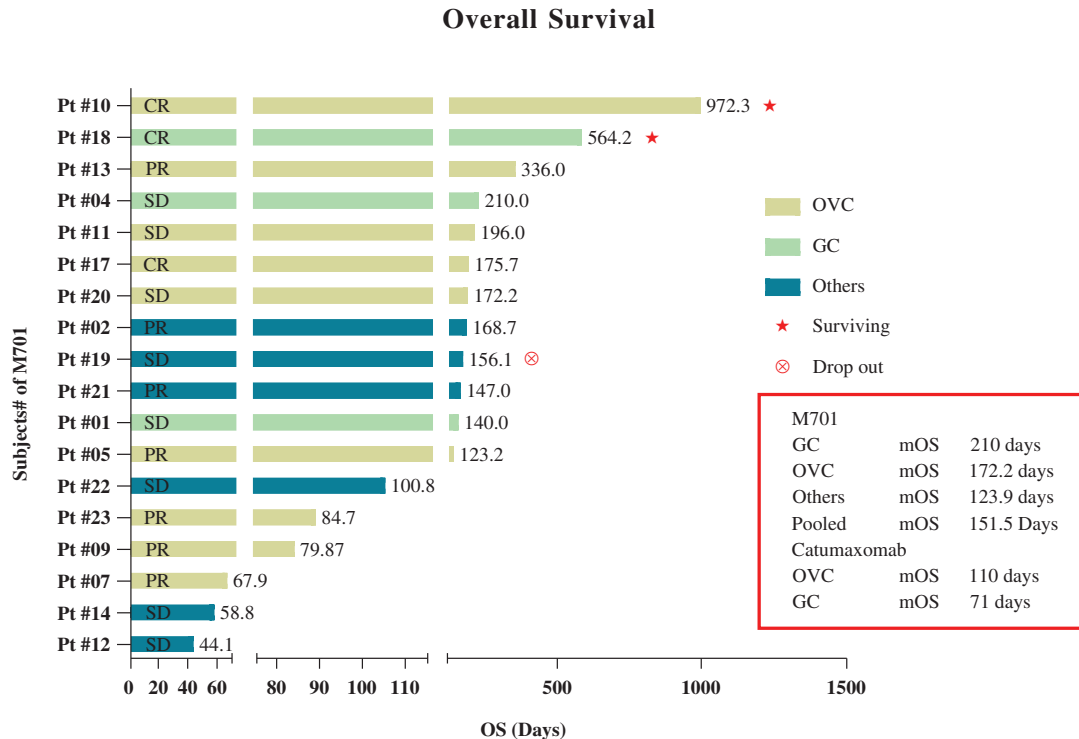
Abbreviation: BOR refers to best of response; GC refers to gastric cancer; OVC refers to ovarian cancer

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Best objective response (BOR) is the best response that is recorded over the course of the trial, from the start of treatment until the progression or relapse of the disease, based on the imaging or other objective evaluation criteria stated in the clinical trial protocol. As there is currently no standard treatment option for MA to be compared with, the evaluation of the BOR of M701 vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. M701’s BOR data surpass the researchers’ expectations formed based on historical data from other treatments for MA in the literature and their own clinical treatment experience, indicating the efficacy of M701.

Furthermore, among the 18 patients who have received at least four times of treatment during the dose-escalation phase, the median overall survival (mOS) reached 151.5 days in this clinical trial. The mOS is the median of all subjects’ overall survival time which is the interval of time from the participation to death or loss to follow-up for a subject. As there is currently no standard treatment option for MA to be compared with, the evaluation of the mOS of M701 vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. M701’s mOS data surpass the researchers’ expectations formed based on historical data from other treatments for MA in the literature and their own clinical treatment experience, indicating the preliminary efficacy for M701.

The following diagram shows the overall survival days for such 18 patients as of October 31, 2022.



Source: Company data; publicly available data

Abbreviations: Pt refers to patient; OVC refers to ovarian cancer; GC refers to gastric cancer.

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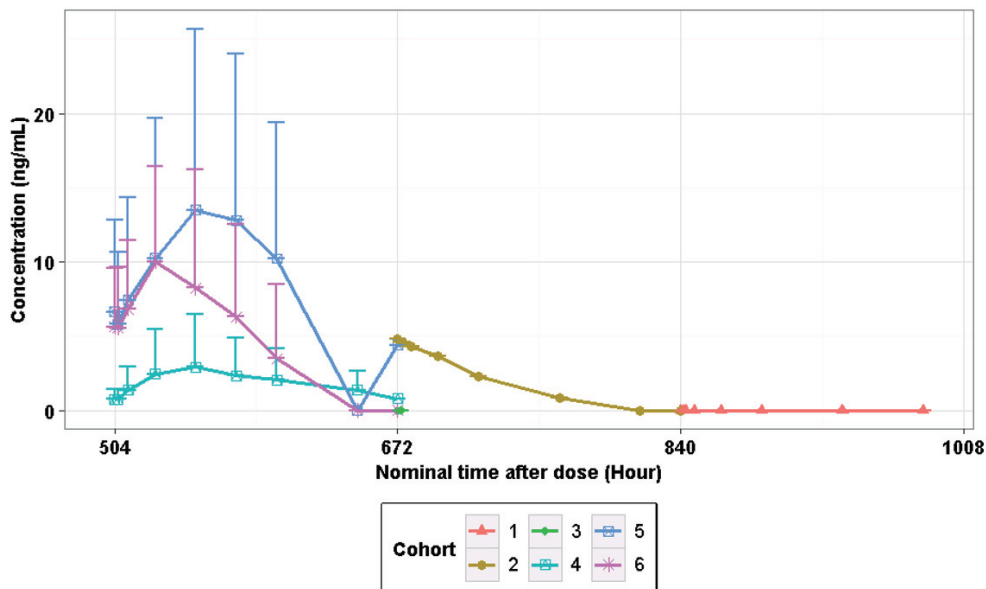
PK/PD results

PK results

The following is a summary of the PK results of M701 in blood samples and ascites samples. The data is presented in the form of a diagram, with the x-axis representing the “nominal time after dose” and the y-axis representing the “concentration of M701.” The diagram below provides a visual representation of the overall PK profile of M701 in blood and ascites samples over time.

PK Results of M701 in Blood Samples

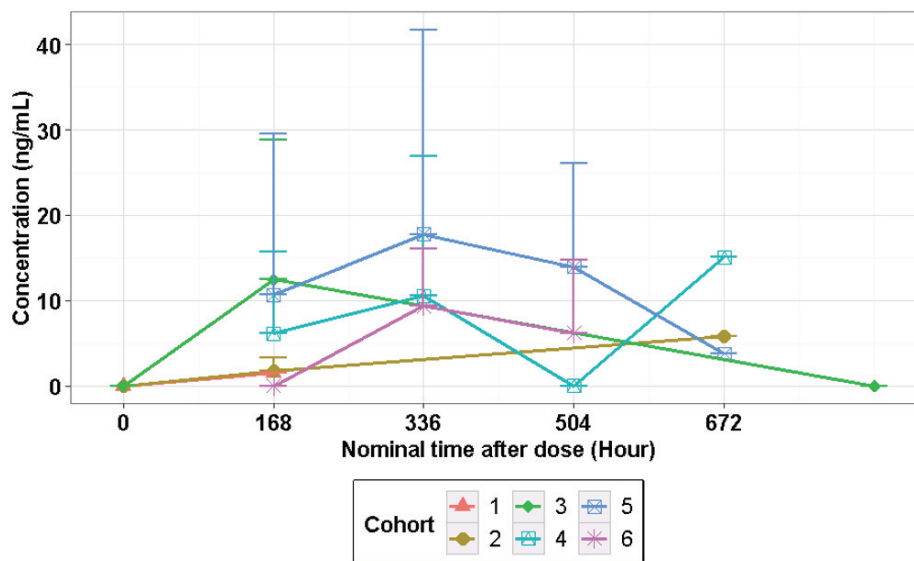
Mean Serum Concentration of M701 – Time Curve after Continuous Intraperitoneal Infusion in Subjects of Different Cohorts



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PK Results of M701 in Ascites Samples

Mean Ascites Concentration of M701 – Time Curve of M701 after Intraperitoneal Infusion in Subjects of Different Cohorts



Cellular PD results

After intraperitoneal administration of the drug, there was a brief decline in the percentage and count of lymphocytes, followed by a rapid recovery, with significant inter-individual variation. There was no significant correlation between the percentage and count of lymphocytes and the dose of the drug administered. Similarly, there was also a brief decline in the percentage and count of monocytes, followed by a rapid recovery, with significant inter-individual variation and no significant correlation between the percentage and count of monocytes and the dose of the drug administered. Additionally, there was a brief increase in the percentage and count of neutrophils, followed by a rapid recovery, with significant inter-individual variation and no significant correlation between the percentage and count of neutrophils and the dose of the drug administered.

The following table presents the cellular PD results of M701 in its Phase I clinical trial by different cohorts.

Cohort (dosage)	Cellular PD results
Cohort 1 (2-5-10-25µg)	After the first dose, the relative lymphocyte count significantly decreased but recovered to baseline before the next dose. Subsequent changes were stable.

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Cohort (dosage)	Cellular PD results
Cohort 2 (25-50µg)	After the first dose, the relative lymphocyte count significantly decreased but recovered to baseline before the next dose. Subsequent changes were stable.
Cohort 3 (50-100µg)	After the first dose, the relative lymphocyte count significantly decreased but recovered to baseline before the next dose. Subsequent changes were stable.
Cohort 4 (50-200µg)	After the first dose, the relative lymphocyte count did not significantly decrease, but recovered to baseline before the next dose. After the second dose, the lymphocyte count did not significantly decrease, but recovered to baseline again. Subsequent changes were stable.
Cohort 5 (50-300µg)	After the first dose, the relative lymphocyte count did not significantly decrease, but recovered to baseline before the next dose. After the second dose, the lymphocyte count did not significantly decrease, but recovered to baseline again. Subsequent changes were stable.
Cohort 6 (50-400µg)	After the first dose, the relative lymphocyte count did not significantly decrease, but recovered to baseline before the next dose. After the second dose, the lymphocyte count did not significantly decrease, but recovered to baseline again. Subsequent changes were stable.

Cytokine PD results

Furthermore, we also analyzed the levels of several cytokines such as IFN γ , TNF α , and IL-6. We observed significant inter-individual variation in the levels of these cytokines. After drug administration, there was a brief decline in the levels of IFN γ and TNF α , followed by a rapid recovery. Additionally, the levels of IFN γ and TNF α were higher in the higher dose cohorts (3-6) compared to lower dose cohorts (1-2). However, there was no significant correlation between the levels of these cytokines and the dose of the drug administered. Also, there was a brief decline in the levels of IL-6, followed by a rapid recovery, with no significant correlation between the levels of IL-6 and the dose of the drug administered.

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The following table presents the cytokine PD results of M701 in its Phase I clinical trial by different cohorts.

Cohort (dosage)	Cytokine PD results
Cohort 1 (2-5-10-25µg)	No significant changes in IFN γ and TNF α after administration; a transient downward trend in IL-6 after the second administration, followed by a rapid recovery and a smooth subsequent change.
Cohort 2 (25-50µg)	No significant changes in IFN γ after administration; a transient downward trend in TNF α after the first administration and after the second administration, followed by rapid recovery and smooth subsequent changes; a transient downward trend in IL-6 after the first administration, followed by rapid recovery and smooth subsequent changes.
Cohort 3 (50-100µg)	Elevated IFN γ after the first dose, followed by recovery to baseline and smooth subsequent changes; transient downward trend of TNF α after the first and second doses, followed by rapid recovery and smooth subsequent changes; transient downward trend of IL-6 after the first dose, followed by rapid recovery and smooth subsequent changes.
Cohort 4 (50-200µg)	IFN γ showed a transient decrease after the second administration, followed by a recovery to baseline and a smooth subsequent change. TNF α showed a transient downward trend after the second administration, followed by a rapid recovery and a smooth subsequent change; IL-6 showed a transient downward trend after the first administration, followed by a rapid recovery and a smooth subsequent change.
Cohort 5 (50-300µg)	Elevated IFN γ after the second administration, followed by recovery to baseline and smooth subsequent changes; transient downward trend of TNF α after the second administration, followed by rapid recovery and smooth subsequent changes; transient downward trend of IL-6 after the first administration, followed by rapid recovery and smooth subsequent changes.

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Cohort (dosage)	Cytokine PD results
Cohort 6 (50-400µg)	Elevated IFN γ after the second administration, followed by recovery to baseline and smooth subsequent changes; a transient downward trend of TNF α after the second administration, followed by rapid recovery and smooth subsequent changes; a transient downward trend of IL-6 after the first administration, followed by rapid recovery and smooth subsequent changes.

Source: Company data

Immunogenicity results

The following table presents the immunogenicity results of M701 in different cohorts. Although there are 23 ADA positive events across 7 cohorts, these events have little impact on the concentrations of M701 in blood and ascites samples over time which means that the presence of ADA have limited influence on M701’s ability to reach its target sites. For more details of the PK results of M701 in blood and ascites samples, please refer to the paragraphs headed “– M701 (EpCAM $\times$ CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Completed Phase I Clinical Trial of M701 Monotherapy for the Treatment of MA in Patients with EpCAM-positive Carcinomas in China – PK/PD Results – PK Results” in this section.

Cohort (dosage)	The number of subjects evaluable for ADA	The number of subjects who tested positive for ADA (and as a percentage of the number of subjects evaluable for ADA)	The number of subjects who tested negative for ADA (and as a percentage of the number of subjects evaluable for ADA)
Cohort 1 (25 µg)	1	1 (100%)	0 (0)
Cohort 2 (50 µg)	4	3 (75%)	1 (25%)
Cohort 3 (100 µg)	4	3 (75%)	1 (25%)
Cohort 4 (200 µg)	3	2 (66.7%)	1 (33.3%)
Cohort 5 (300 µg)	4	4 (100%)	0 (0)
Cohort 6 (400 µg)	11	9 (81.8%)	2 (18.2%)
Cohort 7 (600 µg)	1	1 (100%)	0 (0)
Total	28	23 (82.1%)	5 (17.9%)

Source: Company data

Abbreviation: ADA refers to anti-drug antibodies

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Ongoing Phase II clinical trial of M701 monotherapy in combination with systematic treatment for MA in patients with EpCAM-positive carcinomas in China

Trial design

This is a multicenter, randomized, open-label, controlled Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China. In this clinical trial, subjects receive systematic treatment for the treatment of cancer. As these subjects are suffering from MA caused by their cancer, they are designed to receive M701 monotherapy for the treatment of MA. As advised by our PRC Legal Advisor, pursuant to the “Clinical Trial Technical Guidance Principles for Combination Therapy of Anticancer Drugs” (《抗腫瘤藥物聯合治療臨床試驗技術指導原則》) issued by the CDE, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MA), this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for the single indication of MA. We plan to enroll a total number of 91 to 111 subjects (a) who are advanced ovarian cancer/primary peritoneal carcinoma patients resistant to cisplatin, or advanced gastric cancer or colorectal cancer patients who have failed first-line treatment and second-line treatment, and (b) who have EpCAM-positive ascites with a volume of at least 1L based on a CT evaluation.

To specify the inclusion criteria of “advanced gastric cancer or colorectal cancer patients who have failed first-line treatment and second-line treatment” above, the following table sets forth the standard first-line treatment and second-line treatment for the gastric cancer and colorectal cancer patients.

Cancer Type	First-line treatment	Second-line treatment
Gastric cancer	(1) FOLFOX/XELOX in combination with a PD-1 inhibitor; (2) Oxaliplatin/cisplatin plus fluoropyrimidine; (3) Irinotecan/irinotecan plus fluoropyrimidine; (4) Herceptin in combination with oxaliplatin/cisplatin plus fluorouracil/capecitabine (only for HER2-positive patients).	(1) Single agent chemotherapy (paclitaxel, irinotecan, or vismodegib); (2) For MSI-H patients, pembrolizumab monotherapy.

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Cancer Type	First-line treatment	Second-line treatment
Colorectal cancer	FOLFOX/CAPEOX/FOLFIRI chemotherapy with or without bevacizumab or cetuximab.	(1) PD-1/PD-L1 inhibitors; (2) Combination of different chemotherapy regimens such as ixabepilone, with or without bevacizumab or satuximab as additional treatment

Source: Company data

Patients will be randomized into two groups (treatment arm and control arm) at the ratio of 1:1, with the treatment arm to receive paracentesis plus intra-peritoneal (IP) M701 infusion at an initial dose at 50µg and a maintenance dose at 400µg in combination with systematic treatment, and the control arm to receive only paracentesis in combination with systematic treatment. The following table sets forth the treatment regime in the treatment arm and the control arm:

Tumor types	Control arm	Treatment arm
Advanced gastric cancer	Paracentesis in combination with systematic treatment	Paracentesis plus M701 IP infusion in combination with systematic treatment
Advanced colorectal cancer	Paracentesis in combination with systematic treatment	Paracentesis plus M701 IP infusion in combination with systematic treatment
Advanced ovarian cancer/ primary peritoneal carcinoma	Paracentesis in combination with systematic treatment	Paracentesis plus M701 IP infusion in combination with systematic treatment

Source: Company data

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Details of drugs used in the systematic treatment are as follows:

Tumor types	Drugs used in the systematic treatment	Drug types
Advanced gastric cancer	Apatinib mesylate	Targeted therapy
	Nivolumab (provided that nivolumab will only be used in anti-PD-1 antibody naïve patients)	Immunotherapy
Advanced colorectal cancer	Regorafenib	Targeted therapy
	Fruquintinib	Targeted therapy
Advanced ovarian cancer/ primary peritoneal carcinoma	Paclitaxel	Chemotherapy
	Doxorubicin hydrochloride liposome	Chemotherapy

Source: Company data

The primary objective of this trial is to evaluate the puncture-free survival (PuFS) in MA treatment, while the secondary objectives are to evaluate other efficacy indicators, safety, PK and immunogenicity. The primary endpoint is puncture-free survival (PuFS). The secondary endpoints include ORR, PFS, OS, quality of life, adverse events, PK and immunogenicity.

Trial status

We commenced this trial in December 2021 with CDE confirmation and ethic committee approval. As of March 31, 2023, a total of 53 subjects were enrolled. The following table sets forth the number of subjects enrolled in this Phase II clinical trial of M701 by cancer type as of March 31, 2023.

Cancer types	Number of subjects enrolled for the Phase II clinical trial as of March 31, 2023
Gastric cancer	24
Ovarian cancer (including fallopian tube cancer)	23
Colorectal cancer	5
Primary peritoneal carcinoma	1
Total	53

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We plan to enroll a total of 91 to 111 subjects for this trial. From March 31, 2023 to September 30, 2023, we expect to enroll 10 to 12 subjects each month. We anticipate completing the recruitment of all subjects by September 30, 2023, and reaching the primary endpoint of the trial in the fourth quarter of 2023. We expect the speed of subject enrollment from March to September 2023 to be faster than before, mainly as (i) less impact by the COVID-19 outbreak which resulted in certain delays in our patient recruitment in 2022, and (ii) the expected commencement of subject recruitment by several additional clinical trial centers in the first half of 2023, given the anticipated completion of ethical committee approvals and trial initiation meetings between April and May 2023. As of March 31, 2023, a total of 18 clinical trial centers have initiated subject recruitment for this trial, and by the end of May 2023, it is expected that a total of 34 clinical trial centers will launch the recruitment process.

Interim safety results

As of December 31, 2022, the safety data showed that M701 was well tolerated combined with the systematic treatment. Most of the AEs were Grade 1 or Grade 2 AEs. The incidences of Grade 3 or above TEAEs were 38.9% in M701 arm, in a similar level to that of 38.5% in control arm. The Grade 3 or above TEAEs in M701 arm included hypoalbuminemia, anemia, nausea, hypokalemia, decreased appetite and vomiting. There were only three SAEs related to M701 arm and two of them caused the cessation of treatment. These M701 related SAEs included anorexia, intestinal obstruction and multiple organ dysfunction syndrome.

Ongoing Phase Ib/II clinical trial of M701 monotherapy in combination with systematic treatment for advanced non-small cell lung cancer patients with MPE in China

Trial design

This is a multicenter, open-label Phase Ib/II clinical trial to evaluate the PK/PD, safety, tolerability, and preliminary efficacy of M701 monotherapy in combination with systematic treatment of MPE in advanced non-small cell lung cancer (NSCLC) patients in China. The regimen of the systematic therapy will be decided by the investigators among chemotherapy, target therapy, and immunotherapy. In this clinical trial, subjects receive systematic treatment for the treatment of cancer. As these subjects are suffering from MPE as a result of their cancer, they are designed to receive M701 monotherapy for the treatment of MPE. As advised by our PRC Legal Advisor, pursuant to the “Clinical Trial Technical Guidance Principles for Combination Therapy of Anticancer Drugs” (《抗腫瘤藥物聯合治療臨床試驗技術指導原則》) issued by the CDE, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MPE), this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MPE. We plan to enroll 22 to 36 subjects for the Phase Ib portion and 60 subjects for the Phase II portion.

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The Phase Ib portion consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase will include four cohorts. Cohort 1 will follow the “1+5” design, and cohort 2 to cohort 4 will follow the standard “3+3” design. Subjects in each cohort will undergo a 28-day DLT observation period, receiving an initial dosage of M701 at 25µg on day 1, and escalating dosages of M701 at 50µg, 100µg, 200µg and 400µg for cohort 1, cohort 2, cohort 3 and cohort 4 on day 4, day 7 and day 10, respectively. We plan to enroll 10 to 24 patients in the dose-escalation phase. After determining the RP2D in the dose-escalation phase, the RP2D cohort will be expanded to include an additional three groups (groups A, B and C) of subjects with four subjects in each group. Subjects in groups A, B and C will receive one dosage of M701 every three days for a total of three, four and six dosages, respectively.

The primary objectives of the Phase Ib portion are to evaluate the safety and tolerability of M701, and to determine the RP2D and appropriate dosage frequency of M701 monotherapy in combination with systematic treatment in advanced NSCLC patients with MPE.

In the Phase II portion, patients will be randomized into two groups (treatment arm and control arm) at the ratio of 1:1. The treatment arm will receive M701 intra-pleural infusion plus thoracentesis at RP2D in combination with systematic treatment. The control arm will receive thoracentesis only or thoracentesis and thoracic perfusion chemotherapy, both in combination with systematic treatment.

The primary objective of the Phase II portion is to evaluate the efficacy of M701 monotherapy in combination with systematic treatment in treating MPE for patients with advanced NSCLC.

Trial status

We commenced this trial in November 2022. As of March 31, 2023, a total of 5 subjects had been enrolled for this trial. We expect to complete this trial in the third quarter of 2024. We expect the speed of subject enrollment for this Phase Ib/II trial to be faster than that of the Phase II clinical trial of M701 for MA due to (i) less impact by the COVID-19 outbreak which resulted in certain delays in our patient recruitment in 2022, and (ii) the reduced difficulty in recruiting first-line and later advanced NSCLC patients with MPE compared to second-line and later MA patients.

Clinical Development Plan

MA

We completed a Phase I clinical trial of M701 in monotherapy in treating MA in China in January 2022. We initiated a Phase II clinical trial of M701 monotherapy in combination with systematic treatment in treating MA in China in December 2021. We expect to complete this Phase II trial in the fourth quarter of 2023. For more details, please refer to the paragraphs headed “– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase II Clinical Trial of M701 monotherapy in

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Combination with Systematic Treatment for MA in Patients with EpCAM-positive Carcinomas in China” in this section. After the completion of this Phase II trial, we plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. We expect to receive the BLA approval for M701 monotherapy for the treatment of MA following such submission.

We also received FDA IND approval for our clinical investigation for MA in patients with EpCAM-positive carcinomas in October 2019. We currently have no immediate plan to initiate clinical trial for M701 in the U.S. We plan to leverage our clinical results of Phase II and pivotal/Phase III clinical trials in China to conduct late-stage clinical development of M701 in the U.S. in the future.

We believe it is feasible for us to leverage clinical results of M701 in China to conduct late-stage clinical development of M701 in the U.S. because FDA has released a “Guidance for Industry and FDA Staff/FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions” which provides guidance for the industry and the FDA staff on the acceptance of results generated from foreign clinical studies. This guidance clarifies that sponsors and applicants can demonstrate compliance with the requirements of 21 CFR 312.120 by submitting information evidencing that a foreign clinical study is conducted in accordance with Good Clinical Practice (GCP). As we have been, and will continue to, conduct the clinical trials of M701 in accordance with GCP, we believe the clinical trial results of M701 in China can be used for the application of FDA IND approvals.

Additionally, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guideline “Ethnic Factors in the Acceptability of Foreign Clinical Data E5 (R1)” also supports the use of foreign clinical data as a basis to support the approval of an IND application in a new jurisdiction, without the need to repeat the entire clinical drug development program in the new jurisdiction.

Furthermore, the approval of Zebutinib (developed by BeiGene) by FDA in 2019 primarily based on data from a pivotal Phase II clinical trial conducted in China, as well as data from a global Phase I/II clinical trial, provides a precedent for the acceptance of clinical data generated from clinical trials conducted in China by the FDA.

There have been recent examples of the FDA declining to approve China-tested drugs mainly based on the clinical data generated in China, including sintilimab, a lung cancer drug candidate and surufatinib, a pancreatic and extra-pancreatic neuroendocrine tumor drug candidate. Sintilimab has not undergone any clinical trials in the U.S., while surufatinib has only been tested in a small-scale bridging trial in the U.S. Neither drug has been evaluated in pivotal clinical trials involving diverse populations in the U.S., nor have their pivotal clinical trial protocols been reviewed or approved by the FDA.

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After completing the Phase II clinical trial of M701 and the Phase Ib/II clinical trials of Y101D in China, we plan to leverage the clinical results generated in China to support the late-stage clinical development in the U.S. We plan to collaborate with overseas partners to confirm the design of late-stage clinical trials with FDA and conduct such clinical trials in the U.S., which will enable us to obtain efficacy data encompassing multiple ethnicities and form the basis for us to obtain regulatory approvals to commercialize M701 in the U.S. and some other overseas markets. However, we cannot guarantee that the FDA will accept our clinical results generated in China to support pivotal clinical trials in the U.S., and we may face difficulties and incur additional costs thereof. For details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Commercialization of Our Drug Candidates – We may face difficulties in leveraging the clinical results of our drug candidates in China for late-stage clinical development in other jurisdictions” in this document.

MPE

We commenced a Phase Ib/II clinical trial of M701 for advanced NSCLC patients with MPE in China in November 2022. This trial is designed to evaluate M701 in treating MPE instead of NSCLC. We expect to complete this Phase Ib/II trial in the third quarter of 2024. For more details, please refer to the paragraphs headed “– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase Ib/II Clinical Trial of M701 Monotherapy in Combination with Systematic Treatment for Advanced Non-Small Cell Lung Cancer Patients with MPE in China” in this section. Following the completion of this Phase Ib/II trial, we plan to commence a pivotal/Phase III trial for M701 for the treatment of MPE (instead of NSCLC) in China in the third quarter of 2024 and file BLA submission in the fourth quarter of 2025. We expect to receive the BLA approval for M701 monotherapy for the treatment of MPE (instead of NSCLC) following such submission. We have internally drafted a summary of the design of this pivotal/Phase III clinical trial and plan to submit a consultation with CDE regarding the design in the third quarter of 2024. We expect the speed of subject enrollment for this Phase III trial to be faster than that of the Phase II clinical trial of M701 for MA due to (i) the confirmed dosage and frequency for the Phase III clinical trial, eliminating the need for time-consuming exploration, and (ii) the significantly larger number of clinical trial centers involved in Phase III compared to Phase II.

Solid tumor

We plan to file an IND application with the NMPA in the first quarter of 2024 and expect to receive the IND approval in the second quarter of 2024. We plan to initiate and sponsor a Phase I/II clinical trial of M701 for the treatment of solid tumor in the second quarter of 2024 in China. We expect to conduct a pivotal/Phase III clinical trial and receive the BLA approval for M701 monotherapy for the treatment of solid tumor following the pivotal/Phase III clinical trial and BLA submission for M701 monotherapy for solid tumor.

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Licenses, Rights and Obligations

As we internally discovered and developed M701, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of M701 are as follows:

- We filed the IND application for M701 for MA with the NMPA on August 9, 2016 and received the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials of M701 for MA on February 12, 2018. This IND approval authorized the design of the Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China. The IND approval stipulates that at the time when we plan to conduct a Phase III clinical trial, we should consult with CDE regarding the design of such Phase III clinical trial.
- We filed the IND application for M701 for MA with the FDA on October 2, 2019 and received the IND approval for M701 for MA from the FDA on October 29, 2019.
- We submitted the consultation to the CDE in respect of a Phase II clinical trial of M701 monotherapy in combination with systematic treatment for MA on December 14, 2020. During this consultation, we submitted the interim safety and efficacy data as of November 30, 2020 in the Phase I clinical trial of M701 for the treatment of MA. We received the confirmation from the CDE for the trial design and commencement of this Phase II clinical trial on January 8, 2021. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MA) in this Phase II trial, this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MA. For more details regarding the design of this Phase II clinical trial of M701 monotherapy, please refer to the paragraphs headed “– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase II Clinical Trial of M701 Monotherapy in Combination with Systematic Treatment for MA in Patients with EpCAM-positive Carcinomas in China” in this section. In addition to the above communications with the relevant competent authority, on May 28, 2021, we submitted to the ethic committee the interim safety and efficacy results as of May 8, 2021 from the Phase I clinical trial of M701 for MA, and we received the ethic committee approval for the design and commencement this Phase II clinical trial on June 23, 2021. According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), each phase of clinical drug trials shall be examined and approved by the ethics committee before being carried out. We had sufficient clinical basis to commence this Phase II clinical trial for MA prior to the completion of the Phase I clinical trial of M701 for MA, based on the initial safety

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and efficacy data as of May 8, 2021 of the Phase I clinical trial of M701 for MA, primarily as the main purpose of Phase I trial of M701 for MA is to confirm the safety profile of M701 and determine the RP2D. By May 8, 2021, we have received sufficient safety data to the satisfactory of the ethic committee and the RP2D for the Phase II clinical trial. As advised by Frost & Sullivan, it’s not uncommon to commence a Phase II clinical trial prior to the completion of a prior Phase I clinical trial.

- We submitted the IND application for M701 for MPE with the NMPA on April 19, 2022 and received the IND approval from the NMPA for the Phase Ib/II, Phase III clinical trials of M701 for MPE on July 4, 2022. This IND approval authorized the design of the Phase Ib/II clinical trial of M701 monotherapy in combination with systematic treatment for advanced NSCLC patients with MPE in China. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MPE) in this Phase Ib/II trial, this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MPE. For more details regarding the design of this Phase Ib/II trial of M701 monotherapy for MPE, please refer to the paragraphs headed “– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase Ib/II Clinical Trial of M701 Monotherapy in Combination with Systematic Treatment for Advanced Non-Small Cell Lung Cancer Patients with MPE in China” in this section.

The intended indications of M701 include MA, MPE and solid tumor, which are regarded as three independent indications (instead of indication expansions) mainly due to (a) different administration method (for example, intraperitoneal infusions for MA while intrathoracic infusions for MPE), and (b) different dosing level and schedule designed for each indication. Notwithstanding the foregoing, the safety data, PK/PD data in a clinical trial for one indication of M701 can be leveraged and used as reference in a clinical trial for another indication of M701. However, the efficacy of M701 in different indications will be evaluated independently in different clinical trials.

Therefore, we expect to receive three independent BLA approvals from the NMPA for M701 with respect to each of MA, MPE and solid tumor. With respect to clinical trials for M701 in treating MA, notwithstanding that the Phase I clinical trial evaluated M701 monotherapy in treating MA while the Phase II clinical trial is evaluating M701 monotherapy in combination with systematic treatment for MA, these are regarded as the same clinical program covered by the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials for the study of M701 monotherapy in treating MA, as elaborated above. Therefore, we will only submit one BLA application for M701 monotherapy for MA, and will be able to receive a BLA approval for MA if all the application criteria are met.

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We plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. We expect to receive the BLA approval for M701 monotherapy for the treatment of MA following such submission. The BLA approval for M701 for MA will be limited to the cancer types to be evaluated in the pivotal/Phase III trial of M701 for MA. Based on the cancer types that we evaluated in Phase I and Phase II clinical trials of M701 for MA, we currently expect to include the following cancer types in the pivotal/Phase III trial for M701 for MA: gastric cancer, ovarian cancer, colorectal cancer and peritoneal carcinoma. Therefore, we expect that the BLA approval for M701 in treating MA will be initially limited to the MA caused by these four cancer types. Notwithstanding the foregoing, after the commercialization of M701, physicians may consider using M701 for MA treatment in other cancer types depending on the clinical efficacy of M701 for MA caused by such other cancer types. In addition, we may also expand the clinical application of M701 for MA in other cancer types through post-launch Phase IV clinical studies or through indication-expansion clinical trials.

As of the Latest Practicable Date, we were not aware of any legal claim or proceeding that may have an adverse effect on our development of M701. We had not received any regulatory agency’s concerns or objections to our clinical development plans, completed clinical trial for MA or ongoing clinical trials for MA and MPE as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for M701.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET M701 SUCCESSFULLY.

Y101D (PD-L1 × TGF-β BsAb)

Y101D is a recombinant anti-programmed death ligand-1 (PD-L1) and anti-transforming growth factor-β (TGF-β) humanized BsAb. According to the CDE and the ClinicalTrials.gov websites, Y101D is the only PD-L1 × TGF-β symmetric tetravalent BsAb that has entered into clinical development globally. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document. Therapeutic antibodies targeting PD-1/PD-L1 axis induce potent and durable anti-tumor responses in multiple types of solid tumors. However, only a subset of patients benefits from anti-PD-1/PD-L1 therapies. Y101D is strategically designed to simultaneously inhibit the PD-1/PD-L1 axis and the TGF-β signaling pathways, thus having the potential to unleash a synergistic anti-tumor activity and relieve drug resistance. In our preclinical studies, Y101D has demonstrated potent anti-tumor activity with a favorable safety

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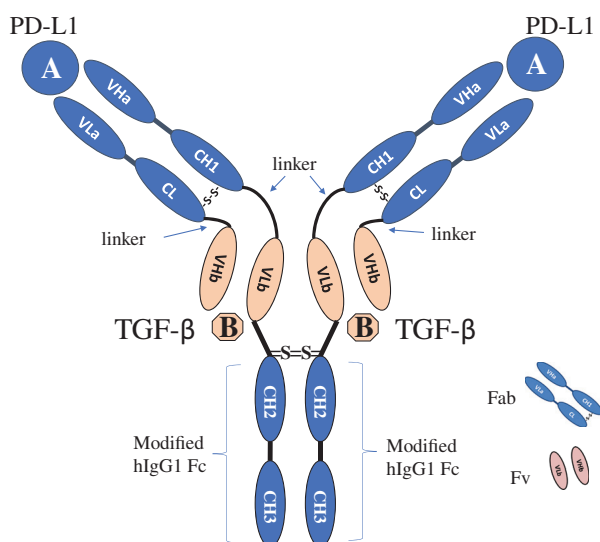
profile, and the anti-TGF- β moiety of Y101D has better stability and biological activity than TGF- β trap *in vivo*. The interim results of the Phase I clinical study for Y101D in patients with metastatic or locally advanced solid tumors in China also show an encouraging safety and efficacy profile for Y101D.

We are currently evaluating Y101D in patients with metastatic or locally advanced solid tumors in a Phase I clinical trial in China. We also commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer in February 2023. In addition, we commenced a Phase Ib/II clinical trial of Y101D in combination with anti-angiogenesis for the treatment of HCC and other advanced solid tumors in March 2023. In addition, we plan to commence the Phase Ib/II clinical trial of Y101D in combination with chemotherapy in treating SCLC in the first quarter of 2024.

We are developing Y101D in-house and own its global IP and commercial rights.

Mechanism of Action

Y101D is a recombinant IgG-like BsAb, which has two identical short chains and two identical long chains, in which short-long chains paired and long-long chains paired. The short chain of Y101D consists of three domains: VL_a, CL, and VH_b, where CL and VH_b are connected through a linker. The VL_a domain is from the VL of an anti-PD-L1 antibody. The VH_b domain is from the VH of an anti-TGF- β antibody. The long chain of Y101D consists of five domains: VH_a, CH1, VL_b, CH2, and CH3, where CH1 and VL_b are connected through a linker. The VH_a domain is from the VH of the anti-PD-L1 antibody, and the VL_b domain is from the VL of the anti-TGF- β antibody. The Fc of Y101D consists of CH2 and CH3 modified from hIgG1 Fc to eliminate the binding to Fc gamma receptors (Fc γ Rs). The diagram below illustrates the molecule structure of Y101D.



Source: Company data

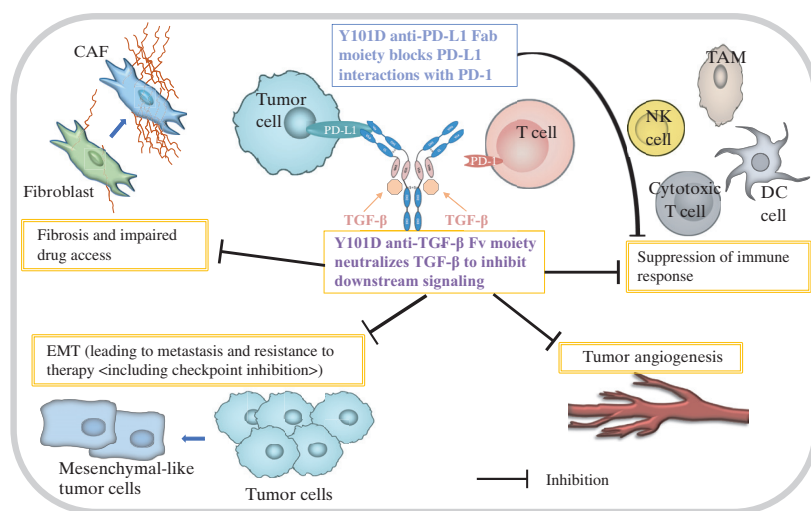
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PD-1 is an inhibitory cell surface receptor expressed on T cells. The binding of PD-1 to its ligand PD-L1 transmits a negative signal that suppresses T cell activity. The normal function of PD-1 is to modulate T cell-mediated immune response in order to prevent the immune system from attacking normal healthy tissue in the body. However, this safeguarding mechanism is often exploited by cancer cells to evade immune surveillance. Many solid tumor cells produce a large amount of PD-L1 to circumvent T cell assaults.

As a versatile cytokine, TGF- β is usually overexpressed in advanced tumors and is related to poor prognoses of the diseases. The role of TGF- β is context-dependent. For pre-malignant cells, TGF- β acts as a tumor suppressor by inhibiting cell proliferation, inducing cell apoptosis, and suppressing inflammation. However, for advanced cancers, TGF- β promotes distant metastasis, drug resistance, and immune escape. TGF- β can regulate the functions of multiple immune cells, such as reducing the cytotoxicity of T cells and natural killer cells (NK cells), inducing the differentiation of regulatory T cells (Tregs), and suppressing the antigen presentation activity of dendritic cells (DCs). TGF- β also restricts the infiltration of immune cells by facilitating peritumoral collagen generation.

Y101D binds to PD-L1 and prevents it from binding to PD-1, thereby restoring the blocked anti-tumor immune response of T cells. Y101D also antagonizes TGF- β , thereby enhancing the tumor-killing activity of multiple immune cells, promoting T cell infiltration by restraining cancer-associated fibroblast (CAF) and collagen generation, counteracting epithelial-mesenchymal transition (EMT), and suppressing tumor angiogenesis. Therefore, by simultaneously inhibiting the PD-1/PD-L1 axis and the TGF- β signaling pathways, Y101D restores the dysregulated anti-tumor immunity of cancer patients and establishes an immunosupportive tumor microenvironment (TME).

The following diagram illustrates the mechanism of action of Y101D:



Source: Company data

Abbreviation: TAM refers to tumor-associated macrophage.

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Market Opportunities and Competition

We are developing Y101D as a monotherapy for the treatment of various types of solid tumors, as well as in combination therapy for the treatment of pancreatic cancer, HCC and other advanced solid tumors.

The incidence of pancreatic cancer in China has grown from approximately 101.5 thousand in 2017 to approximately 115.9 thousand in 2021, and is expected to increase to approximately 133.1 thousand in 2025 and approximately 155.8 thousand in 2030. According to the NCCR and GLOBOCAN, HCC ranked fifth in terms of patient incidence in China in 2021. The incidence of HCC in China has grown from approximately 351.1 thousand in 2017 to approximately 388.0 thousand in 2021, and is expected to further increase to approximately 427.5 thousand in 2025 and 474.2 thousand in 2030.

Therapeutic antibodies that target the PD-1/PD-L1 axis induce potent and durable anti-tumor responses in multiple types of solid tumors. However, only a subset of patients benefits from anti-PD-1/PD-L1 therapies. The response rate of anti-PD-1/PD-L1 mAb in overall patients is far from satisfactory, and most patients show primary or acquired resistance to these immune checkpoint inhibitors. For instance, among various PD-1/PD-L1 approved indications, the overall response rate (ORR) for head and neck squamous cell carcinoma and liver cancer is less than 35% (i.e. over 65% of patients are primary refractory). Microsatellite stable type colorectal cancer, pancreatic cancer, and biliary cancer are less likely to benefit from and are not approved for PD-1/PD-L1 treatment; the median progression-free survival (PFS) for non-squamous and squamous lung cancer is 8-9 months; the median PFS for small cell lung cancer is only 5.2 months; and the median PFS for esophageal squamous cell carcinoma is only 6.9 months, indicating that these patients will develop resistance after treatment for 5-9 months. As a negative regulator of anti-tumor immunity, TGF- β impairs the efficacy of anti-PD-1/PD-L1 drugs and induces resistance. In the TME with hyperactive TGF- β signaling, the effect of anti-PD-1/PD-L1 therapy is limited. Moreover, after receiving anti-PD-1/PD-L1 treatments, the TGF- β 1 gene expression is higher in the tumor tissues of non-responders, resulting in elevated TGF- β levels in their TME, thus forming a vicious cycle.

Correspondingly, the dual blockade of PD-L1 and TGF- β enhances the effect of anti-PD-1/PD-L1 therapies and relieves drug resistance that can benefit patients who (i) are not eligible for PD-1/PD-L1 monotherapy, (ii) failed or developed resistance to PD-1/PD-L1 monotherapy, or (iii) are sensitive to PD-1/PD-L1 yet whose tumors have high levels of TGF- β . Furthermore, anti-PD-L1 and anti-TGF- β BsAbs unleash a synergistic anti-tumor activity, and therefore have the potential to be more efficacious than PD-1/PD-L1 monotherapies, and may replace them as first-line treatment for solid tumors.

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Competitive Landscape

No PD-1/PD-L1 × TGF-β BsAb drug is marketed either globally or in China. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins, according to the CDE and the ClinicalTrials.gov websites. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

The following table summarizes the status of PD-1/PD-L1 × TGF-β pipelines under clinical trials in China as of the Latest Practicable Date:

China Pipeline						
Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase	First Posted Date ⁽¹⁾
M7824	Merck & Co., Inc.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor (including, NSCLC, cholangiocarcinoma, cervical cancer)	III	2022/4/21
SHR-1701	Jiangsu Hengrui Medicine Co Ltd, Shanghai Hengrui Pharmaceutical Co Ltd, Suzhou Suncadia Biopharmaceuticals Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor (including, NSCLC, cervical cancer, gastric cancer)	III	2021/11/17
PM-8001	Biotheus Inc	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	II	2020/6/24
TQB2858	Nanjing Jun Xin Pharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2021/3/25
JS-201	Shanghai Junshi Biosciences Co Ltd	PD-1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/5/21
QLS31901	Qilu Pharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/6/2
Y101D	the Company	PD-L1, TGF-β	BsAb	Metastatic or locally advanced solid tumors; HCC; PC	Ib/II	2022/12/05
BR102	Hisun Biopharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2021/9/13
LBL-015	Nanjing Leads Biolabs Co., Ltd.	PD-1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/9/22
TQB-2868	Nanjing Shunxin Pharmaceuticals Co, Ltd of Chiatai Tianqing Pharmaceutical Group	PD-1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2022/2/14
BJ-005	Boji Biomedical Technology (Hangzhou) Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor; advanced lymphadenoma	I	2022/3/9
GT-90008	Kintor Pharmaceutical (Guangdong) Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/5/31
TST-005	Mabspace Biosciences (Suzhou) Co, Limited	PD-L1, TGF-β	Fusion Protein	Metastatic or locally advanced solid tumors (e.g. HPV positive, NSCLC)	I	2022/7/1
HB-0028	Huabo Biopharm Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/8/9
LY01019	Shandong Boan Biotechnology Co. Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/8/30
6MW3511	Mabwell (Shanghai) Bioscience Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/9/1

Source: NMPA, CDE, Frost & Sullivan Analysis

(1) “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

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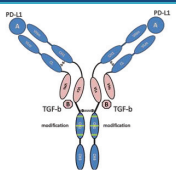
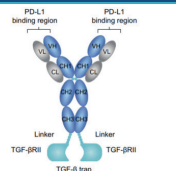
For additional information on the market opportunities and competitive landscape of this drug candidate, please refer to the paragraphs headed “Industry Overview – PD-1/PD-L1 × TGF-β Targeted Drugs Market – Competitive Landscape of PD-1/PD-L1 × TGF-β Targeted Drugs” in this document.

Competitive Advantages

Optimized structural design to target both PD-L1 and TGF-β

In the TME with hyperactive TGF-β signaling, the effect of anti-PD-1/PD-L1 therapy is limited. With the treatment of anti-PD-1/PD-L1 therapy, the TGF-β1 gene expression is higher in the non-responder’s tumor tissues. Correspondingly, the dual blockade of PD-1/PD-L1 and TGF-β has a synergistic anti-tumor activity. Given the independent and complementary immunosuppressive effects of the PD-1/PD-L1 axis and TGF-β, it is rational to block the TGF-β signal to enhance the efficacy of anti-PD-1/PD-L1 to overcome treatment resistance. To optimize the anti-tumor activity of anti-PD-1/PD-L1 therapies, we have developed Y101D, which can simultaneously block the PD-1/PD-L1 and TGF-β pathways.

As shown in the table below, Y101D is a BsAb, whose moiety of anti-TGF-β is from the Fv moiety of an anti-TGF-β antibody, while other PD-1/PD-L1 × TGF-β candidates in clinical trials such as M7824 are bifunctional antibody-receptor fusion proteins whose moieties of binding TGF-β are extracellular domains of TGF-βRII. The diagram below lists Company data of Y101D and publicly available data of M7824, and is not a head-to-head study of Y101D and M7824.

	the Company Y101D ⁽¹⁾	Merck M7824 ⁽²⁾
Format		
Technology	(Fab) ₂ -(Fv) ₂ -Fc, symmetric tetraivalent BsAb with modified Fc of hIgG1	IgG-trap, bifunctional antibody-receptor fusion protein with Fc of wild-type hIgG1
Molecular weight	~200kDa	~180kDa
Affinity	PD-L1: EC50=0.40nM, cell binding TGF-β1: EC50=0.73nM, ELISA TGF-β2: EC50=0.56nM, ELISA TGF-β3: EC50=0.72nM, ELISA	PD-L1: EC50=0.27nM, cell binding TGF-β1: EC50=1.20nM, ELISA TGF-β2: EC50=0.14nM, ELISA TGF-β3: EC50=3.62nM, ELISA
FcγRs binding	No	Yes
Number of glycosylations	1 pair	4 pairs
Stability	Stable at 2-8°C for 27 months and the assessment is continuing	Not available

Source: (1) Company data;

(2) the reference “Lan et al., *Sci. Transl. Med.* 10, eaan5488 (2018)”

Abbreviation: EC50 refers to half maximal effective concentration.

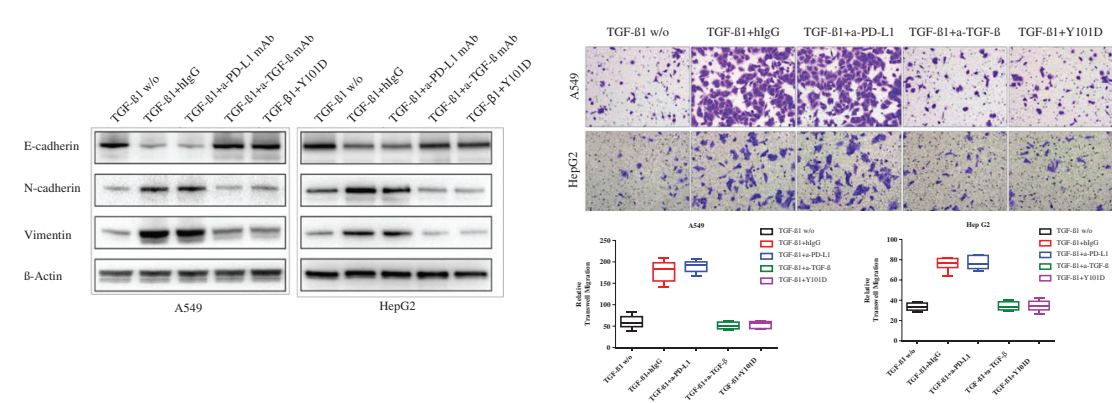
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Effectively counteracted the biological effects of TGF-β pathway

In vitro experiments show that Y101D can effectively counteract the biological effects of TGF-β pathways, including inducing EMT, and immunosuppression.

Y101D can inhibit TGF-β-induced EMT and cell migration. TGF-β enhances the movement capability and promotes EMT in cancer cells. Consistent with previous observations, TGF-β1 decreases epithelial markers as it increases the expression of mesenchymal markers in A549 (human lung cancer cell) and HepG2 (human HCC cell) cells. Y101D effectively antagonizes the TGF-β1-induced EMT in A549 and HepG2 cells: upregulating the epithelial marker (E-cadherin) and downregulating mesenchymal markers (N-cadherin and Vimentin). At the same time, an anti-PD-L1 antibody does not affect the EMT in cancer cells.

Y101D inhibits TGF-β1-induced EMT and cell migration



Source: Company data

Abbreviation: w/o refers to without.

The study also shows that Y101D inhibits the migration of A549 and HepG2 cancer cells enhanced by TGF-β1. The following table shows the migration rates of A549 and HepG2 cancer cells induced by various test samples:

Sample	A549 cells	HepG2 cells
	migration rate (%)	migration rate (%)
TGF-β1 w/o	59.83	33.50
TGF-β1+hIgG	178.83	75.83
TGF-β1+anti-PD-L1 mAb	189.83	76.83
TGF-β1+anti-TGF-β mAb	51.33	34.17
TGF-β1+Y101D	54.33	34.50

Source: Company data

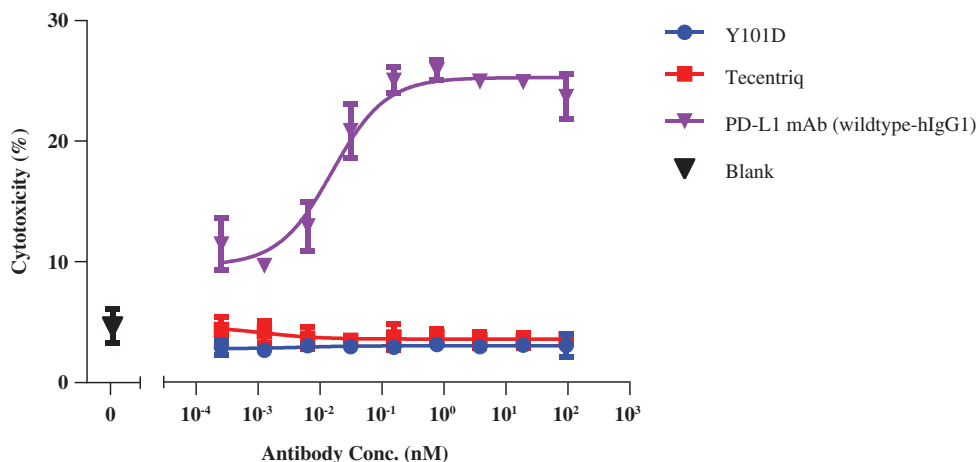
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Y101D can also reverse the TGF- β caused immunosuppression. TGF- β cooperates with IL-2 to induce Foxp3 expression and promotes the conversion of naïve T cells to Tregs. Tregs are immune-suppressive T cells. Y101D blocks the negative effects of TGF- β 1 on T cells: it reversed proliferation inhibition, decreased the ratio of G1, and counteracted cell apoptosis. Furthermore, TGF- β 1 substantially reshaped the cytokine pattern during T cell activation. Most cytokines, such as Th1-associated (IL-2) and pro-inflammatory cytokines (IFN- γ), are downregulated by exogenous TGF- β 1. Y101D almost completely antagonizes the TGF- β 1-caused changes in the cytokine release.

No ADCC activity on PD-L1 expressing T cells

Normally, the Fc region of an antibody binds to FcR, which is generally expressed at high levels on NK cells. As PD-L1 is also expressed on activated T cells, an anti-PD-L1 antibody can also lead to the killing of these activated T cells in a tumor via ADCC as it can bind to PD-L1 on T cells and Fc γ Rs on NK cells simultaneously. To address this issue, we have introduced several mutations to the Fc region of Y101D to disable its binding to the Fc γ Rs. Leveraging this well-designed structure, Y101D does not elicit ADCC, antibody-dependent cell-mediated phagocytosis (ADCP) or CDC activity on PD-L1 expressing T cells. As shown in the diagram below, the Fc region of Y101D is modified to remove the binding to Fc γ Rs and the ADCC function. In addition, the killing activities mediated by Fc γ Rs via other cells such as macrophage are also eliminated.

The Fc of Y101D is modified to remove the binding to Fc γ Rs and the ADCC function



Source: Company data

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The following table shows the Fc-mediated ADCC effect (measured by the maximum lysis percentage and the EC50 value) of samples on PD-L1 positive H358 cells with NK cells used as effector cells.

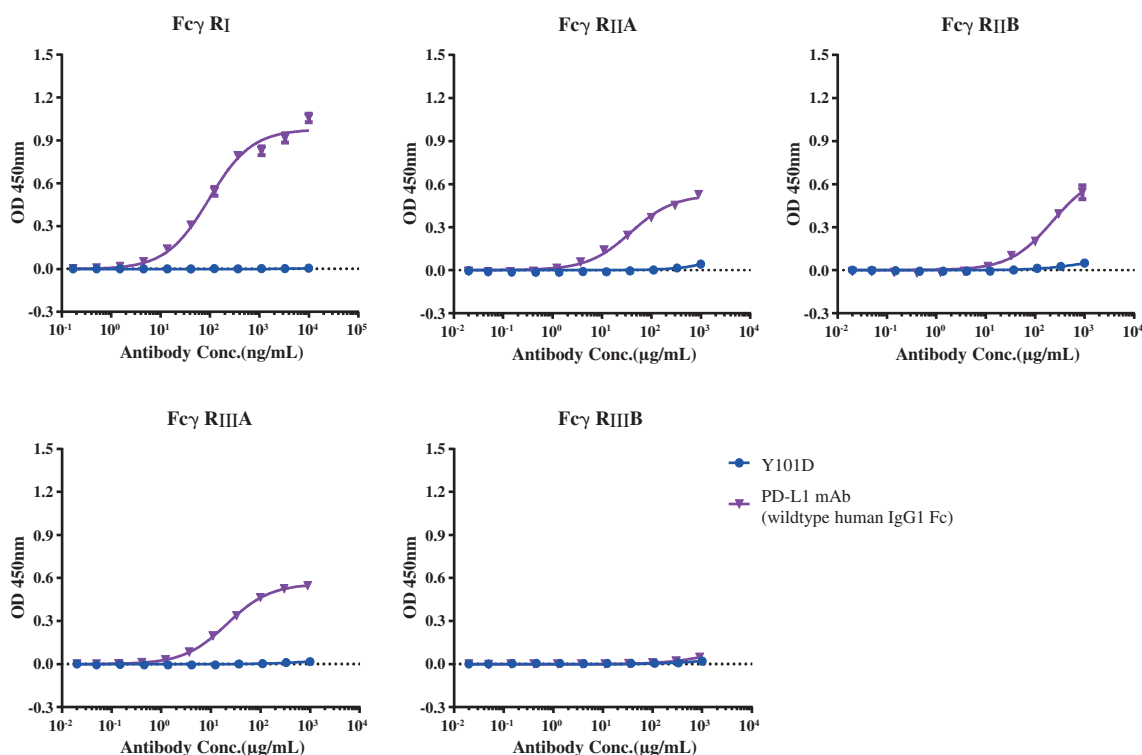
Sample	Maximum lysis (%)	EC50 (nM)
Y101D	2.9	–
Tecentriq	3.5	–
PD-L1 mAb	25.1	0.01604

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

In an *in vitro* study to detect the Fc-mediated effector function of Y101D, Y101D does not bind to any of the following five FcγRs: FcγRI, FcγRIIA, FcγRIIB, FcγRIIIA, and FcγRIIIB in ELISA. Also, it does not induce ADCC activities to PD-L1 positive cell line H358.

The following graphs and table show the binding effect of the Fc of Y101D and PD-L1 mAb on FcγR.



Sample	FcγRI	FcγRIIA	FcγRIIB	FcγRIIIA	FcγRIIIB
	EC50				
Y101D	–	–	–	–	–
PD-L1 mAb	95.4ng/mL	38.3μg/mL	225.5μg/mL	21.27μg/mL	–

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

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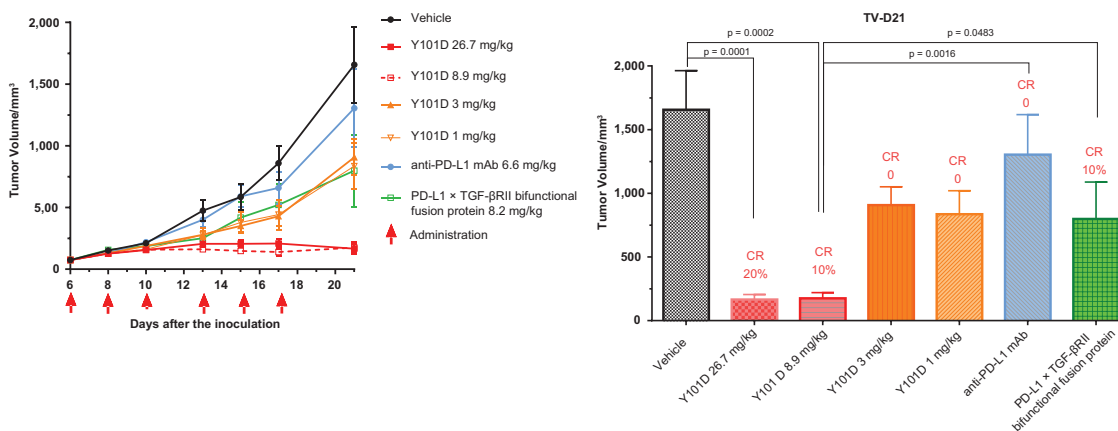
Dual blockade of TGF- β and PD-1/PD-L1 which lead to potent anti-tumor effect

The immune normalization strategy aims to recover the blocked anti-tumor immune response. For certain patients, normalizing a single vital pathway such as PD-1/PD-L1 is sufficient to trigger the reshape of the TME. However, for most patients, immune deficiency or dysregulation in the TME is often multifaceted and correcting other defects might be necessary to overcome the resistance to anti-PD-1/PD-L1 therapy. Based on the fact that TGF- β is the dominant inhibitory pathway, the dual blockade of TGF- β and PD-1/PD-L1 by Y101D can effectively alter the “cancer-immunity set point,” converting immune tolerance to activated T cell immunity.

In vivo experiment indicates that, in the EMT-6 breast orthotopic tumor model, the anti-tumor activity of Y101D is superior to that of anti-PD-L1 monotherapy and PD-L1 $\times$ TGF- β R2 bifunctional fusion protein. We compared the anti-tumor effect of Y101D (8.9 mg/kg) with other controls, including vehicle, anti-PD-L1 mAb (6.6 mg/kg) and PD-L1 $\times$ TGF- β R2 bifunctional fusion protein (8.2 mg/kg). In the EMT-6 orthotopic tumor model, the anti-PD-L1 antibody does not exhibit a significant anti-tumor effect, the anti-tumor activity of Y101D is superior to vehicle ($p = 0.0002$), the anti-PD-L1 antibody ($p = 0.0016$), and PD-L1 $\times$ TGF- β R2 bifunctional fusion protein ($p = 0.0483$). The higher dose of Y101D had better efficacy. In particular, Y101D (26.7mg/kg) treatment led to 20% CR.

The diagrams and table below present the efficacy of anti-PD-L1 mAb, PD-L1 $\times$ TGF- β R2 bifunctional fusion protein, and different doses of Y101D in suppressing tumor growth in the EMT-6 breast orthotopic tumor model 21 days after inoculation.

In the EMT-6 breast orthotopic tumor model The efficacy of Y101D was better than that of PD-L1 $\times$ TGF- β R2 bifunctional fusion protein



Source: Company data

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Drug	Dose (mg/kg)	CR	The average tumor volume (mm ³)	Tumor growth inhibition rate	P-value (compared with the vehicle)
Vehicle	–	0%	1,656.54	0.00%	–
Y101D	26.7	20%	166.17	89.97%	0.0001
Y101D	8.9	10%	175.40	89.41%	0.0002
Y101D	3	0%	907.20	45.23%	0.0405
Y101D	1	0%	835.40	49.57%	0.0343
Anti-PD-L1 mAb	6.6	0%	1,304.12	21.27%	0.4343
PD-L1 × TGF-βRII bifunctional fusion protein	8.2	10%	798.31	51.81%	0.0574

Source: Company data

Favorable safety profile

As of December 31, 2022, data obtained from the Phase I study demonstrated that Y101D was well-tolerated. MTD was not reached up to 30 mg/kg. Most of the AEs were Grade 1 or Grade 2 AEs. Only two SAEs have been observed (both were bleeding) in two patients, and such patients have recovered.

Summary of Clinical Trial Results

We initiated a Phase I clinical trial for Y101D in patients with metastatic or locally advanced solid tumors in China in August 2021. This trial is currently ongoing.

Trial design

This is a multicenter, open-label, dose-escalation Phase I trial. The primary objectives of this trial are to evaluate the safety and tolerability of Y101D (including observing DLT, and determining MTD and RP2D). The secondary objectives are to evaluate the PK/PD profile, immunogenicity, and preliminary efficacy of Y101D. The primary endpoints include safety and tolerability, and secondary endpoints include PK/PD profile, immunogenicity, ORR, time in therapeutic range, DCR, DOR, PFS, and OS.

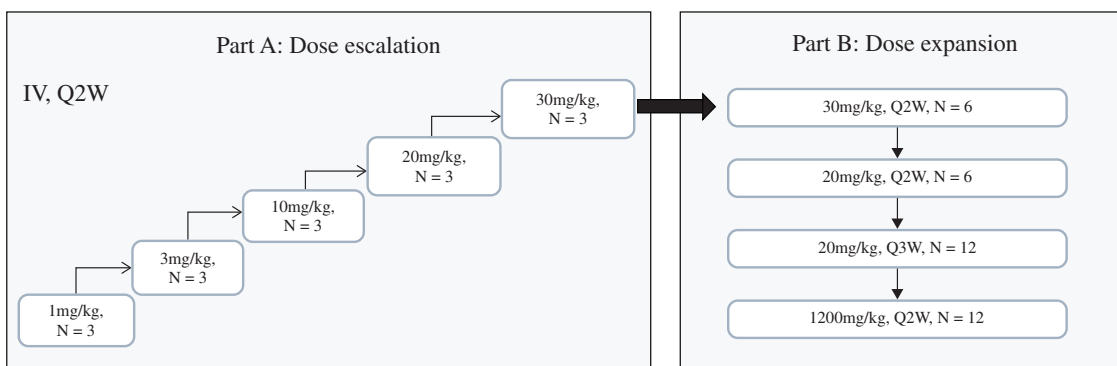
This trial consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase followed the standard “3+3” protocol, with five escalating dose levels set at 1 mg/kg, 3 mg/kg, 10 mg/kg, 20 mg/kg, and 30 mg/kg, respectively. Each cohort includes three subjects. Subjects in each cohort will receive a biweekly dosage for a four-week DLT

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observation period. Subjects who complete the four-week DLT observation period may, at the discretion of the investigator, enter an extended treatment period until disease progression or intolerable toxicity is observed. We plan to enroll 15 to 30 patients in the dose-escalation phase.

After determining the MTD in the dose-escalation phase, the MTD cohort will be expanded to include an additional three to six subjects. If the MTD is not observed at cohort five (30 mg/kg), the investigator may decide to continue with the dose-escalation and explore higher dose levels, or expand the cohort at certain dose levels. In addition, if the investigator observes clinical benefits for subjects in certain cohort(s), the investigator may expand such cohort(s) to include subjects with one to three different tumor types, provided that each expanded cohort will not exceed 30 subjects.

The following diagram illustrates the design of Y101D Phase I clinical trial:



Source: Company data

Abbreviations: IV refers to intravenous injection; Q2W refers to every two weeks.

Trial status

We initiated this Phase I clinical trial in August 2021. As of March 31, 2023, a total of 40 patients had been enrolled in the dose-escalation phase and the cohort-expansion phase. We expect to complete this Phase I clinical trial in the fourth quarter of 2023.

Interim safety results

As of December 31, 2022, data obtained from the Phase I study demonstrated that Y101D was well-tolerated. MTD was not reached up to 30 mg/kg. MTD, or maximum tolerated dose, refers to the highest dose cohort in which no Grade 3 or above AEs as specified in the clinical trial protocol which is considered to be possibly or definitely related to the medication (DLT) are observed in the Phase I clinical trial. It is the highest dose of the medication that can be tolerated by the study participants. This trial is still in its dose escalation phase, and the MTD has not been decided yet.

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Most of the AEs were Grade 1 or Grade 2 AEs. Only two SAEs have been observed (both are bleeding) in two patients, and such patients have recovered.

The following table sets forth the number of patients experiencing TRAEs by different cohorts as of December 31, 2022.

	Grade 1 TRAEs	Grade 2 TRAEs	Grade 3 TRAEs
Cohort 1	1	1	0
Cohort 2	2	1	0
Cohort 3	1	2	0
Cohort 4	3	2	0
Cohort 5	8	5	2
Total	15	11	2

Source: Company data

Note: Each patient in the trial may experience multiple incidences of TRAEs in different grades. For example, a patient experienced both Grade 1 and Grade 2 TRAEs will be counted toward the number of Grade 1 and Grade 2 TRAEs at the same time. Therefore, although only 18 patients experienced TRAEs in this trial, the number of patients experiencing TRAEs is presented as 28 in this table.

The following table presents the symptoms of TRAEs by different cohorts as of December 31, 2022.

	Symptoms
Grade 1 TRAEs	Oral mucositis, disseminated rash, gingival bleeding, thyrotoxicosis, elevation of lipase, diarrhea, dry mouth, proteinuria, epistaxis, muscle pain, elevation of alkaline phosphatase, elevation of thyroxine, increase in fatigue, nausea, poor appetite, etc.
Grade 2 TRAEs	Rash, hyperthyroidism, elevated levels of lipase, prolonged QTc interval, decreased platelet count, anemia that worsens, low sodium levels, increased levels of alanine aminotransferase, urticaria-associated pruritus, epistaxis, etc.
Grade 3 TRAEs	Elevated levels of gamma-glutamyl transpeptidase, nosebleed.

Source: Company data

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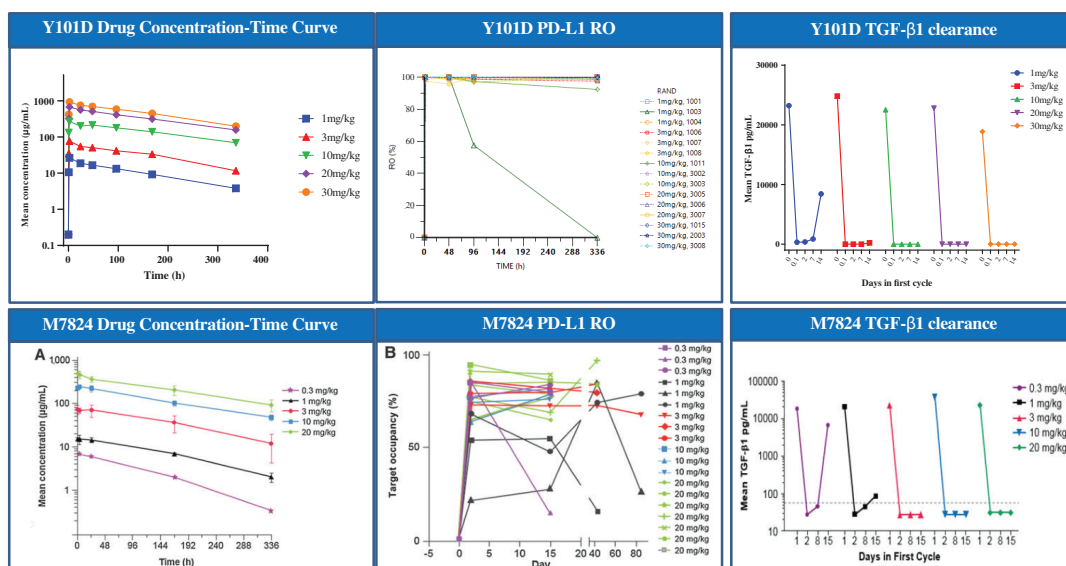
Interim efficacy results

As of December 31, 2022, one refractory Peritoneal Mesothelioma patient has reached a progression-free survival (PFS) of 13 months, showing the preliminary antitumor activity of Y101D. PFS is the total duration of time from the start of treatment until the progression or relapse of the disease, as determined by imaging or other objective evaluation criteria specified in the clinical trial protocol. As there is currently no standard treatment option for metastatic or locally advanced solid tumors to be compared with, the evaluation of the PFS of Y101D vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. Y101D’s PFS data surpass the researchers’ expectations formed based on historical data from other treatments for metastatic or locally advanced solid tumors in the literature and their own clinical treatment experience, indicating the preliminary efficacy for Y101D.

Interim PK/PD results

As of December 31, 2022, data obtained from the Phase I study shows a favorable PK/PD profile of Y101D. The C_{max} and the t_{1/2} are as shown below diagram. Y101D can occupy the PD-L1 epitope for 100% and completely (100%) eliminate the TGF-β1/2/3 at 3mg/kg.

The following diagram shows the PK/PD characters of Y101D and M7824.



Source: (1) Company data;

(2) Published M7824 phase I clinical data (Clin Cancer Res. 2018 Mar 15;24(6):1287-1295.)

Abbreviation: RO refers to receptor occupancy.

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The following table presents the immunogenicity results of Y101D in different cohorts as of December 31, 2022.

Cohort (dosage)	The number of subjects evaluable for ADA	The number of subjects who tested positive for ADA (and as a percentage of the number of subjects evaluable for ADA)	The number of subjects who tested negative for ADA (and as a percentage of the number of subjects evaluable for ADA)
Cohort 1 (1mg/kg)	3	2 (66.67%)	1 (33.33%)
Cohort 2 (3mg/kg)	3	3 (100%)	0 (0)
Cohort 3 (10mg/kg)	3	1 (33.33%)	2 (66.67%)
Cohort 4 (20mg/kg)	3	1 (33.33%)	2 (66.67%)
Cohort 5 (30mg/kg)	8	2 (25%)	6 (75%)
Total	20	9 (45%)	11 (55%)

Source: Company data

Abbreviation: ADA refers to anti-drug antibodies

Clinical Development Plan

Y101D as a monotherapy in patients with metastatic or locally advanced solid tumors in China

We expect to complete the Phase I clinical trial for Y101D in patients with metastatic or locally advanced solid tumors in China in the fourth quarter of 2023. We will continue to explore the potentials of Y101D as a monotherapy.

Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients

We obtained the ethic committee and IND approvals for a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China in November and December 2022, respectively. We commenced this trial in February 2023 and expect to complete this trial by the first quarter of 2025. As of March 31, 2023, we have enrolled 8 subjects for this trial. Following the completion of this Phase Ib/II clinical trial, we also plan to commence a Phase III clinical trial in the fourth quarter of 2024 and expect to complete this trial by the second quarter of 2026.

This is a multicenter, open-label Phase Ib/II clinical trial to evaluate the safety, tolerability, and preliminary efficacy of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China. The Phase Ib portion consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase includes two cohorts, both of which follow the standard “3+3”

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design to receive (a) two escalating dose levels of Y101D at 20 mg/kg and 30 mg/kg (Day 1, Q3W), respectively, and (b) gemcitabine (manufactured by Hansoh Pharmaceutical Group Company Limited with a selling price of RMB210/g) at 1,000mg/m² (Day 1, Day 8, Q3W) and albumin paclitaxel (manufactured by CSPC Ouyi Pharmaceutical Co., Ltd. with a selling price of RMB700/100mg) at 125mg/m² (Day 1, Day 8, Q3W). Subjects in each cohort will undergo a three-week DLT observation period. After completing the safety assessment for cohort 1 and cohort 2, the investigator may decide to conduct dose-expansion studies for one or two cohorts. We plan to enroll 12 to 36 subjects for the Phase Ib trial.

Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China

We obtained the ethic committee and IND approvals for a Phase Ib/II clinical trial of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China in December 2022. We commenced this trial in March 2023 and expect to complete this trial by the second quarter of 2025. As of March 31, 2023, we have enrolled 3 subjects for this trial. Following the completion of this Phase Ib/II clinical trial, we also plan to commence a Phase III clinical trial.

This is a multicenter, open-label Phase Ib/II clinical trial to evaluate the safety and preliminary efficacy of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China. The Phase Ib portion consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase will include three cohorts, with each cohort following the standard “3+3” design. Subjects in these three cohorts will receive (a) escalating dose levels of Y101D at 10mg/kg, 20 mg/kg and 30 mg/kg Q3W, respectively, and (b) bevacizumab at 15mg/kg (Q3W). Subjects in each cohort will undergo a three-week DLT observation period. After determining MTD in the dose-escalation phase, the investigator may decide to conduct dose-expansion studies for HCC patients for one or two cohorts. We plan to enroll 29 to 38 subjects in the Phase Ib portion, including 20 subjects in the cohort-expansion phase. The RP2D of Y101D determined in the Phase Ib portion will be used in the Phase II portion. The Phase II portion includes a screening period of 28 days, a treatment period, and a follow-up period. We plan to enroll 47 to 82 subjects for the Phase II portion.

The primary objectives of the Phase Ib portion are to evaluate the safety and tolerability of Y101D in combination with bevacizumab (manufactured by Roche with a selling price of RMB2,050/100mg) in treating HCC and other advanced solid tumors, and to determine the RP2D. The primary objective of the Phase II portion is to evaluate the efficacy of Y101D in combination with bevacizumab in treating HCC.

Y101D in combination with chemotherapy in treating SCLC

We plan to file an IND application with the NMPA in the third quarter of 2023 and expect to receive the IND approval in that quarter. We plan to commence a Phase Ib/II clinical trial of Y101D in combination with chemotherapy in treating SCLC in the first quarter of 2024. The specific combination drug of the trial will be decided prior to the commencement of the trial.

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FDA IND approval

In addition, we received FDA IND approval for our clinical investigation of Y101D for solid tumors in January 2021. We currently have no immediate plan to initiate clinical trial for Y101D in the U.S. We plan to leverage our clinical results of Y101D in China for further clinical development of Y101D in the U.S. in the future.

We believe it is feasible for us to leverage clinical results of Y101D in China to conduct late-stage clinical development of Y101D in the U.S. because (i) FDA has released a “Guidance for Industry and FDA Staff/FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions” which provides guidance for the industry and the FDA staff on the acceptance of results generated from foreign clinical studies; and (ii) the ICH guideline “Ethnic Factors in the Acceptability of Foreign Clinical Data E5 (R1)” which supports the use of foreign clinical data as a basis to support the approval of an IND application in a new jurisdiction, without the need to repeat the entire clinical drug development program in the new jurisdiction.

There have been recent examples of the FDA declining to approve China-tested drugs mainly based on the clinical data generated in China, including sintilimab, a lung cancer drug candidate and surufatinib, a pancreatic and extra-pancreatic neuroendocrine tumor drug candidate. Sintilimab has not undergone any clinical trials in the U.S., while surufatinib has only been tested in a small-scale bridging trial in the U.S. Neither drug has been involved in pivotal clinical trials involving diverse populations in the U.S., nor have their pivotal clinical trial protocols been reviewed or approved by the FDA.

After completing the Phase II clinical trial of M701 and the Phase Ib/II clinical trials of Y101D in China, we plan to leverage the clinical results generated in China to support the late-stage clinical development in the U.S. We plan to collaborate with overseas partners to confirm the design of late-stage clinical trials with FDA and conduct such clinical trials in the U.S., which will enable us to obtain efficacy data encompassing multiple ethnicities and form the basis for us to obtain regulatory approvals to commercialize M701 in the U.S. and some other overseas markets. For more details, please refer to the analysis in the paragraphs headed “– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Clinical Development Plan”. However, we cannot guarantee that the FDA will accept our clinical results generated in China to support pivotal clinical trials in the U.S., and we may face difficulties and incur additional costs thereof. For details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Commercialization of Our Drug Candidates – We may face difficulties in leveraging the clinical results of our drug candidates in China for late-stage clinical development in other jurisdictions” in this document.

Licenses, Rights and Obligations

As we internally discovered and developed Y101D, we maintain the global rights to develop and commercialize this drug candidate.

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Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of Y101D are as follows:

- We filed the IND application for Y101D for solid tumors with the NMPA on February 24, 2021 and received the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials of Y101D for solid tumors on May 18, 2021.
- We filed the IND application for Y101D for solid tumors with the FDA on December 23, 2020 and received the IND approval for Y101D for solid tumors from FDA on January 21, 2021.
- We submitted the IND application for Y101D for advanced/metastatic pancreatic cancer in combination therapy with gemcitabine and albumin paclitaxel with the NMPA on September 9, 2022 and received the umbrella IND approval from the NMPA for the Phase Ib/II, Phase III clinical trials of Y101D for advanced/metastatic pancreatic cancer in combination therapy with gemcitabine and albumin paclitaxel on December 5, 2022.
- We submitted the IND application for Y101D for HCC and other advanced solid tumors in combination therapy with bevacizumab with the NMPA on October 19, 2022 and received the umbrella IND approval from the NMPA for the Phase Ib/II, Phase III clinical trials of Y101D for HCC and other advanced solid tumors in combination therapy with bevacizumab paclitaxel on December 29, 2022.

We had not received any regulatory agency’s concerns or objections to our clinical development plans or any ongoing clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for Y101D.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y101D SUCCESSFULLY.

Y150 (CD38 × CD3 BsAb)

Y150 is a recombinant BsAb based on our YBODY[®] platform that consists of a fully human anti-CD38 Fab-Fc moiety and a humanized anti-CD3 scFv-Fc moiety. According to the CDE website, Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. There is no evidence that

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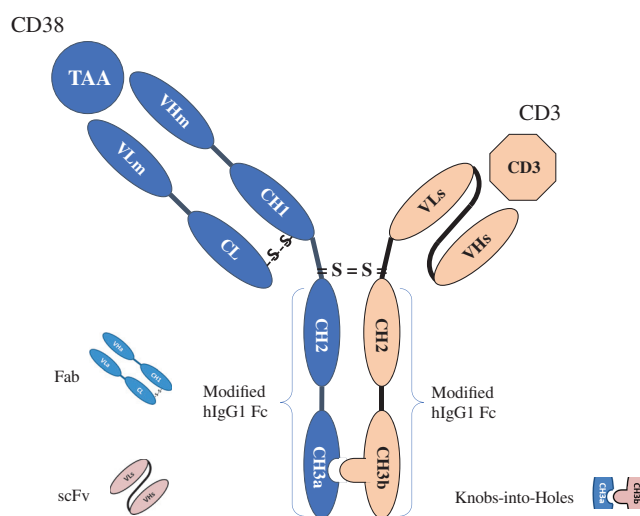
BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document. Y150 simultaneously binds CD38 antigen on target tumor cells and the CD3 antigen on T cells, bringing them into spatial proximity, allowing activated T cells to attack target tumor cells.

We are currently evaluating Y150 in a Phase I clinical trial in rrMM in China. We will further explore the clinical efficacy of Y150 monotherapy in treating rrMM patients as well as its potentials in combination therapy. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We also plan to initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM.

We are developing Y150 in-house and own its global IP and commercial rights.

Mechanism of Action

Y150 is a recombinant, IgG1-like BsAb consisting of a fully human anti-CD38 Fab-Fc and a humanized anti-CD3 scFv-Fc, with the Fc region of Y150 modified to eliminate binding to FcγRs. The diagram below illustrates the molecule structure of Y150.

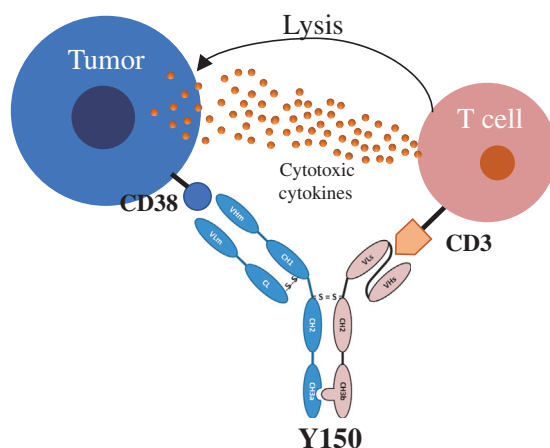


Source: Company data

CD38 is expressed at low levels on normal healthy tissues, while at high levels on multiple myeloma (MM) and lymphoma cells, suggesting its potential as a tumor target to treat hematological malignancies, especially MM. CD3 is a protein complex and T cell co-receptor that directly activates cytotoxic T cells and T helper cells, in association with T cell antigen recognition receptor (TCR).

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Y150 is designed to simultaneously target CD38 antigen on tumor cells and CD3 antigen on T cells. Upon binding, the antibody bridges the effector and the target cells, bringing them together into spatial proximity to activate T cells, allowing for the activated T cells to attack the target cells and enhance their anti-cancer activities. The following diagram illustrates the mechanism of action of Y150:



Market Opportunities and Competition

MM is a cancer of the plasma cells in the bone marrow. Plasma cells are antibody-producing white blood cells that are critical to the immune system. Myeloma begins when healthy plasma cells become cancerous and grow out of control. MM often results in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.

The incidence of MM in China exhibits a much faster growth trend partly due to the fast-growing aging population in China. The incidence of MM increased from 19.5 thousand in 2017 to 21.7 thousand in 2021 at a CAGR of 2.7%. With the increasing aging population in China, the incidence of MM is expected to grow to 24.5 thousand in 2025 at a CAGR of 3.1% from 2021 and further to 27.7 thousand in 2030 at a CAGR of 2.5% from 2025. The diagnostic rate of MM in China is relatively low due to the complicated diagnostic process and lack of accessibility to effective diagnostic methods.

Current treatment and limitations

The prognosis of an MM patient is very heterogeneous and is subject to various factors, such as genetics, performance status and stage of disease, which in turn can determine the treatment and management of the disease. Current treatment regimens can prolong patient survival; however, MM remains incurable, and patients will eventually relapse and succumb to their disease, and for most of the patients, MM will eventually develop into rrMM. As a result, patients may require continuous treatment in order to manage MM as a chronic disease and treatment regimens with convenient administration would be preferred. Existing treatment options with different mechanisms of action are usually exhausted early on in the treatment, as patients are treated with doublet and triplet combination regimens in early treatment lines. Therefore, new classes of therapy with innovative mechanisms of action are required for patients who relapse or who are refractory to the current classes of drugs. There are a few new classes of MM therapy, for example, the antibody drug conjugate that targets the B cell

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maturation antigens, which can reach an ORR of 31% as a third or later-line treatment, and 73% of the patients who responded to the treatment continued to respond at month six, and selective inhibitors of nuclear exports such as selinexor. However, such new classes of MM therapies may not be able to completely cure MM. In recent years, the clinical application of Thalidomide, Lenalidomide, Bortezomib and CD38 mAbs has greatly improved the remission rate of multiple myeloma, however, these drugs cannot completely avoid the relapse caused by minimal residual disease. Those patients still do not have effective drug to use.

Given that approximately 16.2 thousand and 117.1 thousand deaths were caused by MM in China and globally in 2020, respectively, there remains a need for patients whose disease has relapsed after, or is refractory to, available MM therapies. We believe Y150, leveraging its well-designed structure to simultaneously target CD38 antigen on tumor cells and CD3 antigen on T cells, has the potential to serve as a therapy for the treatment of MM patients who relapse or otherwise become refractory to the existing therapies.

Competitive landscape

CD38 is an emerging target for the treatment of MM. As a result, there are multiple CD38 targeted antibodies being developed for the treatment of MM. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively.

The development of CD38 targeted BsAb is still at its emerging stage. However, there is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document. The following table sets forth the competitive landscape of CD38 targeted BsAbs for the treatment of MM globally as of the Latest Practicable Date:

Global Pipeline							
Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date ⁽¹⁾
Y150	the Company	CD38, CD3	BsAb	Multiple myeloma	Global	FDA IND Approval	\
					China	I	2021/5/28
ISB 1442	Ichnos Sciences SA	CD38, CD47	BsAb	Multiple myeloma	Global	I/II	2022/6/22
ISB 1342	Ichnos Sciences SA, Glenmark Pharmaceuticals S.A.	CD38, CD3	BsAb	Multiple myeloma	Global	I	2017/10/13
SG2501	Hangzhou Sumgen Biotech Co., Ltd.	CD38, CD47	BsAb	Relapsed or Refractory Hematological Malignancies and Lymphoma	Global	I	2022/3/24

Source: NMPA, CDE, ClinicalTrials.gov, FDA, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

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Several competing molecules of Y150 target CD47 in addition to CD38. Both CD38 and CD47 are highly expressed on MM cells and serve as negative regulators of immune cells. However, CD38 has enzymatic activity, modulating the immune system and transmitting signals through its metabolites, while CD47 is an immune checkpoint and inhibits macrophage phagocytosis and immune response through its interaction with macrophages.

For additional information on the market opportunities and competitive landscape of this drug candidate, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – CD38 × CD3 Targeted BsAbs” in this document.

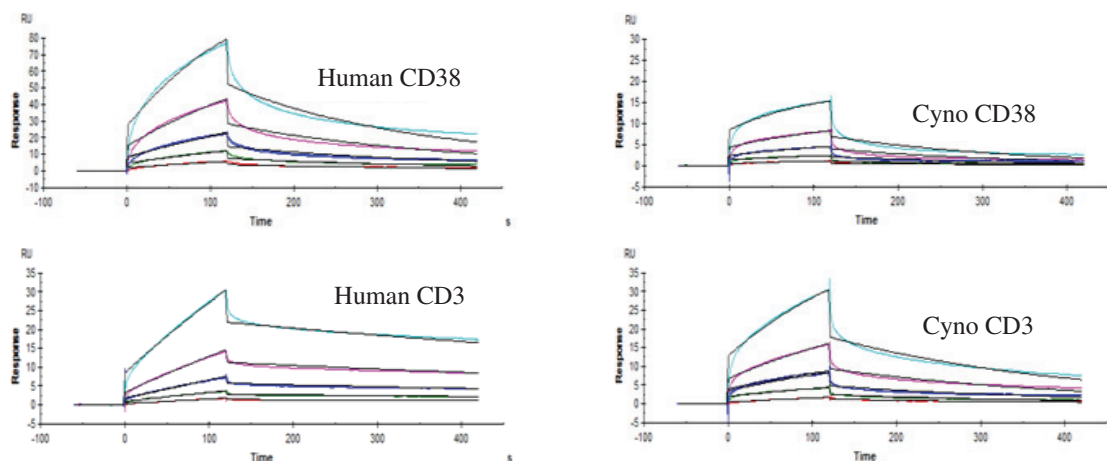
Competitive Advantages

Well-designed structure to avoid inducing on-target but off-tumor toxicity

Targets for tumor recognition such as CD38 are not only highly expressed on tumor cells but are also ubiquitously detected on healthy tissues. Consequently, highly potent T cell-engaging BsAbs bear the risk of inducing on-target, but off-tumor toxicity by attacking normal healthy cells, limiting the achievement of dose levels needed for optimal anti-tumor activity.

Y150 is a bispecific monoclonal antibody that consists of a fully human anti-CD38 Fab-Fc and a humanized anti-CD3 scFv-Fc, with the Fc region modified from hIgG1. Knobs-into-Holes (KIH) mutations are introduced into the Fc region to maximize heterodimer formation. In order to avoid non-specific immune activation, we also introduce mutations into the Fc region to reduce the FcγRs’ binding activity. In addition, we specifically modifies the CD38-binding domain of Y150 to equip it with reduced CD38 affinity, allowing it to selectively recognize CD38-positive tumor cells without attacking normal healthy cells with low CD38 expression.

Y150 has monkey species cross-reactivity and binds to both human and cynomolgus monkey antigens CD38 and CD3 with moderate affinity



Source: Company data

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The table below presents the binding affinities of Y150 towards human and monkey CD38 and CD3 using a surface plasmon resonance (SPR) assay. The results show that Y150 exhibits moderate binding affinities towards both human and monkey CD38 and CD3, with binding constant of 100nM.

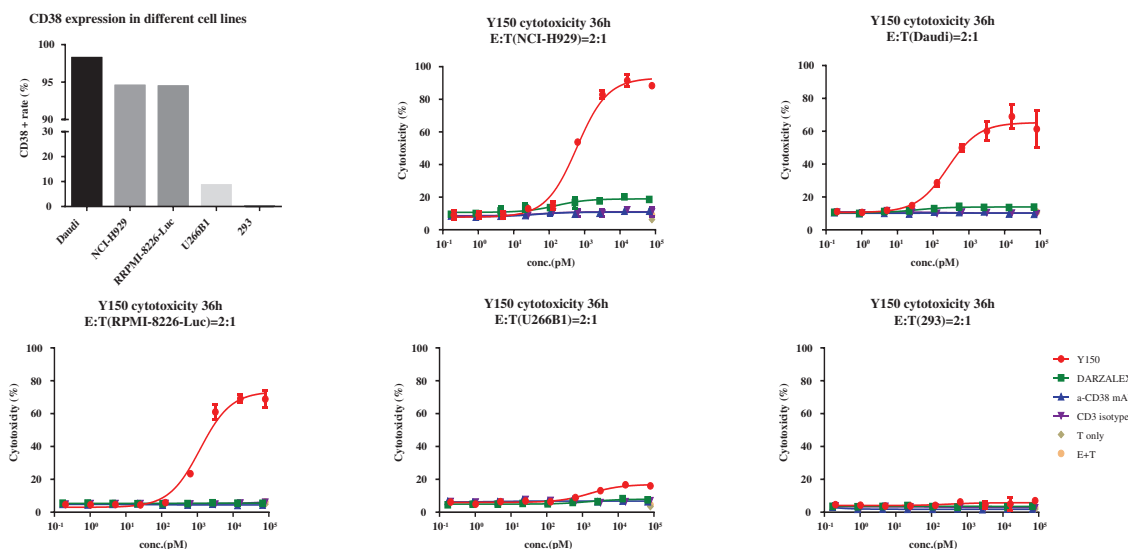
Antibody	Antigen	k_a (1/Ms)	k_d (1/s)	K_D (M)
Y150	Human CD38	9.447E+04	1.119E-02	1.184E-07
Y150	Human CD3	5.161E+04	9.544E-03	1.849E-07
Y150	Cynomolgus CD38	3.064E+04	4.568E-03	1.491E-07
Y150	Cynomolgus CD3	1.058E+04	3.451E-03	3.262E-07

Source: Company data

Abbreviation: k_a refers to the association rate constant, the rate at which the analyte binds to the ligand, measured in inverse milliseconds (1/Ms); k_d refers to the dissociation rate constant, the rate at which the analyte dissociates from the ligand, measured in inverse seconds (1/s); K_D refers to the equilibrium dissociation constant, the ratio of the dissociation constant to the association constant, measured in molar (M).

As shown below, the study has demonstrated significant cytotoxicity of Y150 against high-expressing CD38 cell lines such as RPMI-8226-Luc cells, Daudi and NCI-H929 cells with the maximum killing potential of 73.5%, 65.3% and 93.2%, respectively. The cytotoxicity of Y150 against the low-CD38 expressing U266B1 line was low with a maximum killing potential of 16.9%. Y150 did not mediate any significant cell death effect in CD38 negative HEK293 cells. These results have demonstrated that Y150 may stimulate T cell mediated cytotoxicity of CD38-expressing cells in a dose-dependent manner. The susceptibility of cancer cells to Y150 correlates with the surface expression levels of CD38.

Y150-mediated cytotoxicity to various target cells with different CD38 expression levels



Source: Company data

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The table below presents the Y150-mediated cytotoxicity to various target cells with descending CD38 expression levels in our head-to-head pre-clinical studies:

Sample	Daudi		NCI-H929		RPMI-8226-Luc		U266B1		293	
	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)
Y150	65.3	258.3	93.16	607.2	73.53	1,189	16.92	1,641	5.781	—
DARZALEX	13.94	—	18.97	156.4	5.572	—	7.966	1,481	3.506	—
Anti-CD38 mAb	10.21	—	10.79	—	4.422	—	6.818	4.339	1.817	—
CD3 isotype	10.28	—	11.05	—	7.154	—	—	—	2.908	—

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

Potent *in vitro* and *in vivo* efficacy

A series of *in vitro* studies were conducted to fully elucidate the binding and relevant functional characteristics of Y150 that contribute to its ability of T cell activation and cytotoxicity. These studies demonstrate that, among others, (a) Y150 has the ability to promote CD3-positive cell-to-CD38-positive cell association, followed by a significant increase in the subpopulations of activated cytotoxic T cells; (b) Y150 exhibits a robust cytotoxic effect in the presence of CD3-positive effectors and various types of CD38-positive cancer cells; and (c) Y150 can induce its cytotoxic effect through T cell activation rather than through ADCC, ADCP, CDC or PCD mechanisms of cytotoxicity.

These mechanisms of Y150 are further demonstrated in *in vivo* efficacy experiments in xenograft murine models of human malignancies, in which Y150 is able to inhibit the growth of pre-established human Burkitt’s lymphoma and multiple myeloma tumors in a dose-dependent manner.

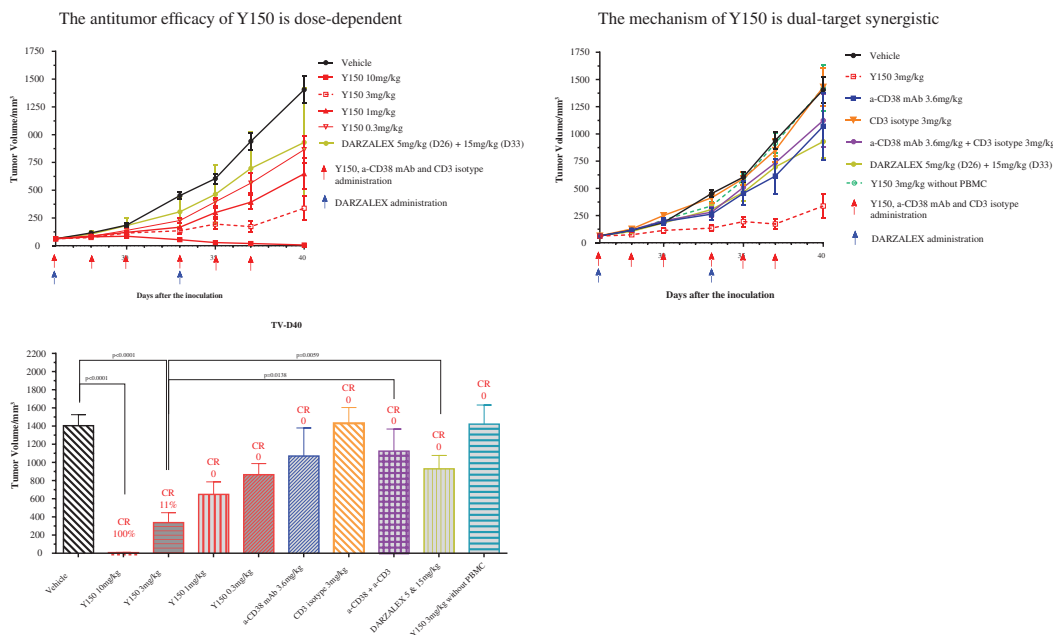
In the *in vivo* efficacy experiment to evaluate the growth inhibition effect of Y150 against pre-established CD38-positive human Burkitt’s lymphoma Daudi cells in immunocompromised NPG mice that were reconstituted with human PBMCs, dose-dependent tumor growth inhibition is observed in the Y150 treated groups. On study day 40, the rate of tumor growth inhibition reaches 38%, 54%, 76% and 100% in animals received 0.3mg/kg, 1mg/kg, 3mg/kg and 10 mg/kg of Y150, respectively. Moreover, the CR of the Y150 (10mg/kg) treated group is 100%. Treatment with ≥ 3 mg/kg Y150 is more efficacious than Darzalex (a CD38 antibody developed by Janssen Biotech), 3.6 mg/kg of an anti-CD38 mAb, 3 mg/kg of CD3 isotype, or a combination of an anti-CD38 mAb and a CD3 isotype, all of which suggests the physical closeness of activated T cells to CD38-positive target cells is important.

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The diagram and table below present the efficacy of different doses of Y150, anti-CD38 mAb, CD3 isotype, anti-CD38+CD3 isotype and DARZALEX in suppressing tumor growth in the Daudi subcutaneous tumor model 40 days after inoculation in our head-to-head pre-clinical studies:

In the human Burkitt's lymphoma Daudi subcutaneous tumor model

The efficacy of Y150 was better than that of Darzalex in our head-to-head pre-clinical studies



Source: Company data

Drug	Dose (mg/kg)	CR	The average tumor volume (mm ³)	Tumor growth inhibition rate	P-value (compared with the vehicle)
Vehicle	N/A	0%	1,404.92	0%	N/A
Y150	10	100%	6.74	100%	<0.0001
Y150	3	11%	337.6	76%	<0.0001
Y150	1	0%	648.26	54%	0.0006
Y150	0.3	0%	865.6	38%	0.0061
Anti-CD38 mAb	3.6	0%	1,070.3	24%	0.2936
CD3 isotype	3	0%	1,430.85	-2%	0.9037
Anti-CD38+CD3 isotype	3.6+3	0%	1,123.78	20%	0.3142
DARZALEX	5+15	0%	930.19	34%	0.0215
Y150 w/o PBMC	3	0%	1,421.09	-1%	0.9444

Source: Company data

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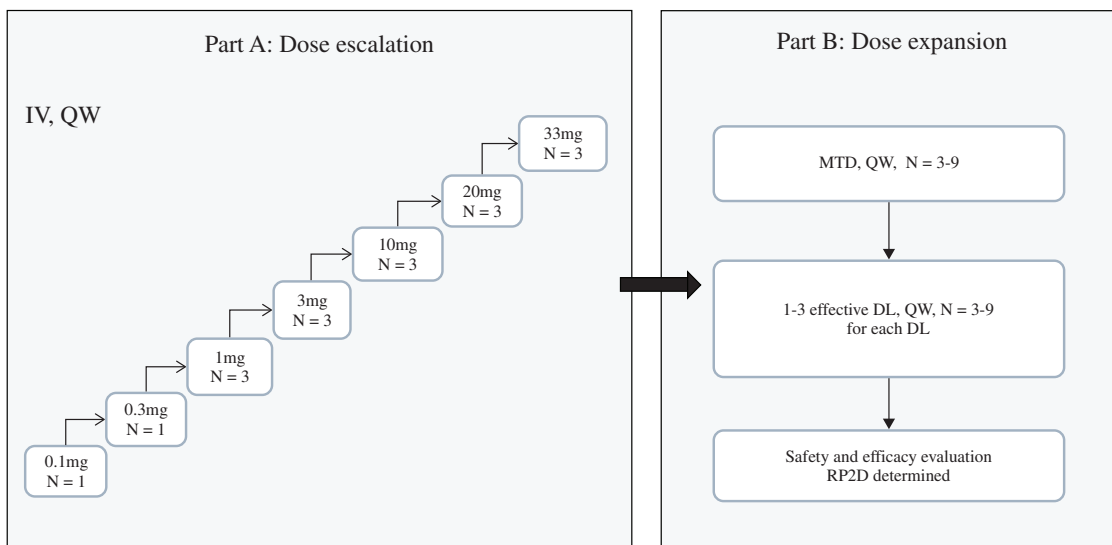
Summary of Clinical Trial Results

We initiated a Phase I clinical trial of Y150 in rrMM in China in August 2021. We are currently enrolling patients.

Trial design

This is a multicenter, open-label, dose-escalation Phase I trial to evaluate the safety, tolerability, pharmacokinetic, immunogenicity and preliminary efficacy of Y150 in subjects with rrMM. We plan to enroll a total number of 23 to 78 patients in this study. This trial includes a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase consists of an accelerated titration phase and a traditional “3+3” dose-escalation phase. In the accelerated titration phase, patients will be enrolled in two cohorts to receive escalating dose levels from 0.1mg to 0.3mg. In the traditional “3+3” dose-escalation phase, patients will be enrolled in five dose cohorts (at maximum dose level of 1mg, 3mg, 10mg, 20mg and 33 mg, respectively). If the MTD is not reached, the maximum administered dose (MAD) will be 33mg. Once the MTD or MAD is reached, the RP2D will be determined. An additional 3-9 subjects might be enrolled at MTD/MAD to ensure that at least 9 patients are in the cohort.

The primary endpoints include safety and tolerability, and the determination of MTD and RP2D. Secondary endpoints include PK/PD profile, efficacy evaluation, and immunogenicity. The following diagram shows the design of Y150 Phase I clinical trial:



Source: Company data

Abbreviations: IV refers to intravenous injection; QW refers to once every week.

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Trial status

We initiated this Phase I clinical trial for Y150 in August 2021. As of March 31, 2023, a total of 17 patients had been enrolled in the first five cohorts of the dose-escalation phase. We expect to complete this Phase I clinical trial in the first quarter of 2024.

Interim safety results

As of December 31, 2022, data obtained from the Phase I study demonstrated that Y150 was generally well tolerated. Only one subject with DLT was observed at 1mg and had recovered without treatment. Y150 is well tolerated among the other 13 subjects enrolled. The MTD was not reached up to 3 mg. MTD, or maximum tolerated dose, refers to the highest dose cohort in which no Grade 3 or above AEs as specified in the clinical trial protocol which is considered to be possibly or definitely related to the medication (DLT) are observed in a Phase I clinical trial. It is the highest dose of the medication that can be tolerated by the study participants. This trial is still in its dose escalation phase, and the MTD has not been decided yet. The majority of TRAEs observed were Grade 1 and 2.

The following table sets forth the number of patients experiencing TRAEs by different cohorts as of December 31, 2022.

	Grade 1 TRAEs	Grade 2 TRAEs	Grade 3 TRAEs	Grade 4 TRAEs
Cohort 1	1	1	0	0
Cohort 2	1	1	1	0
Cohort 3	6	6	4	3
Cohort 4	3	3	2	1
Total	11	11	7	4

Source: Company data

Note: Each patient in the trial may experience multiple incidences of TRAEs in different grades. For example, a patient experienced both Grade 1 and Grade 2 TRAEs will be counted toward the number of Grade 1 and Grade 2 TRAEs at the same time.

The following table presents the symptoms of TRAEs by different cohorts as of December 31, 2022.

	Symptoms
Grade 1 TRAEs	Biliary colic, nausea, abdominal mass, prolonged activated partial thromboplastin time, local edema, prolonged prothrombin time, vomiting, insomnia, decreased appetite, elevation of aspartate transaminase, elevation of bilirubin, decrease in fibrinogen, decrease in white blood cell count, difficulty breathing, etc.

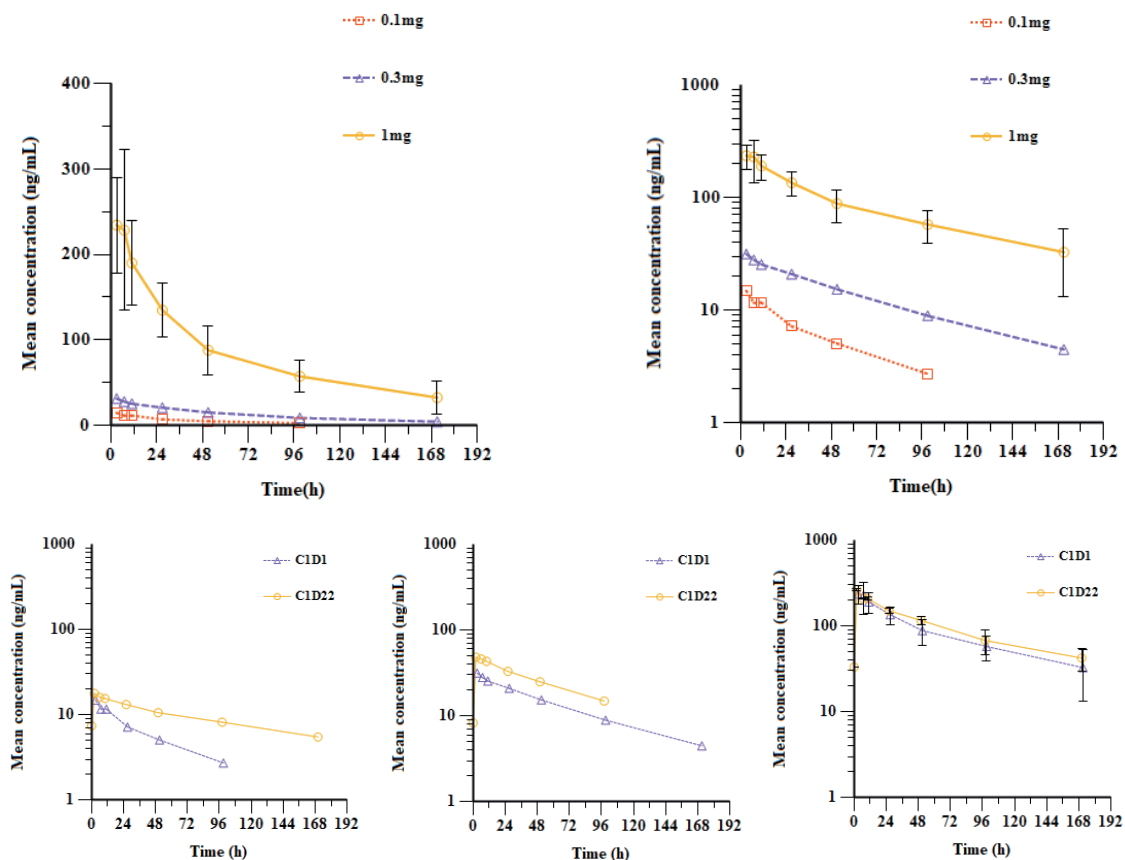
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Symptoms

Grade 2 TRAEs	Gastrointestinal distention, biliary colic, elevation of bilirubin, decrease in fibrinogen, epistaxis, tachycardia, coughing, decrease in platelet count, hypoproteinemia, decrease in neutrophil count, decrease in white blood cell count, anemia, fever, pain, etc.
Grade 3 TRAEs	Decreased appetite, decrease in platelet count, hypertension, hypokalemia, decrease in white blood cell count, anemia, elevation of aspartate transaminase, heart failure, hypoproteinemia, decrease in fibrinogen, decrease in neutrophil count.
Grade 4 TRAEs	Myocarditis, decrease in white blood cell count, decrease in platelet count, decrease in neutrophil count, decrease in platelet count.

Source: Company data

The following Y150 semi-logarithmic mean concentration-time curves for single and multiple doses of Y150 present the interim PK results of the Y150 over time in its Phase I clinical trial.



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The following table presents the interim PD results of Y150 in its Phase I clinical trial by different cohorts.

Cohort (dosage)	Cytokine PD results
Cohort 1 (0.1mg)	After the first administration, there was a 1-2 fold increase in IL-6, IL-8, and IL-10 levels compared to baseline. These levels began to increase 8 hours after administration, reached a peak at 24 hours, and returned to baseline by 48 hours. The second administration of the drug resulted in a 2-3 fold increase in IL-6 and IL-8 levels compared to baseline. These levels began to increase 4-8 hours after administration, reached a peak at 24-48 hours, and returned to baseline by 24-48 hours. Activation of CD69+ T cells was not significant, but there was an abnormal increase in the proportion of CD38+ B cells.
Cohort 2 (0.3mg)	After first administration, IL-6, IL-8, and IL-10 levels increased 1-2 fold compared to baseline. These levels began to increase 0-4 hours after administration, reached a peak at 24-48 hours, and returned to baseline by 24-48 hours. Activation of CD69+ T cells increased 24-48 hours after administration, and the proportion of CD38+ B cells decreased 24-48 hours after administration.
Cohort 3 (1mg)	In one patient, IL-6 levels reached a maximum of 40,000 pg/ml (1280 times the baseline level), while in the other three patients, IL-6 levels peaked at 700-1000 pg/ml (235 times the baseline level). In the remaining 3 patients, IL-6 levels increased 3-6 fold. There was significant individual variability. Cell factors were most significantly released after the first administration of the drug, with a transient release that peaked 4 hours after the end of the administration and returned to baseline by 24-48 hours. Activation of CD69+ T cells increased significantly 24-48 hours after administration, and the proportion of CD38+ B cells decreased significantly 24-48 hours after administration, with significant individual variability.
Cohort 4 (3mg)	The peak of cytokine IL-6 was between 1420-3035pg/ml (around 150-fold baseline). In one patient, IL-6 peak was at 8150pg/ml (880-fold baseline), and the activation was obvious. After the 1st drug administration, the cytokine reached peak level at 8-24h, then released transiently, and gradually recovered at 48h. Subpopulation of CD69+T lymphocytes had a significantly activation at 24h after drug administration, while the proportion of CD38+B cells decreased significantly at 24-48h after drug administration with large individual differences.

Source: Company data

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The following table presents the immunogenicity results of Y150 in different cohorts.

Cohort (dosage)	The number of subjects evaluable for ADA	The number of subjects who tested positive for ADA (and as a percentage of the number of subjects evaluable for ADA)	The number of subjects who tested negative for ADA (and as a percentage of the number of subjects evaluable for ADA)
1 (0.1mg)	1	0 (0)	1 (100%)
2 (0.3mg)	1	0 (0)	1 (100%)
3 (1 mg)	4	1 (25%)	3 (75%)
Total	6	1 (16.7%)	5 (83.3%)

Source: Company data

Abbreviation: ADA refers to anti-drug antibodies

The results show that the incidence of ADA is low across all the evaluated cohorts, and no significant difference in the incidence of ADA were observed between the different cohorts. These results suggest that Y150 is well tolerated and has a low immunogenic potential, which is a favorable characteristic for a therapeutic BsAb.

Clinical Development Plan

We expect to complete the Phase I clinical trial of Y150 in rrMM in China in the first quarter of 2024. We will further explore the clinical efficacy of Y150 monotherapy in treating rrMM patients as well as its potentials in combination therapy. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We plan to file an IND application with the NMPA in the second quarter of 2024 and expect to receive the IND approval in the third quarter of 2024. In addition, we also plan to initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM. Specific manufacturer(s) of the combination drug lenalidomide will be decided prior to the commencement of the trial.

Furthermore, we received FDA IND approval for our clinical investigation of Y150 for rrMM in August 2020. We currently have no immediate plan to initiate clinical trial for Y150 in the U.S. We plan to leverage our clinical results of Y150 in China for further clinical development of Y150 in the U.S. in the future.

We believe it is feasible for us to leverage clinical results of Y150 in China to conduct late-stage clinical development of Y150 in the U.S. because (i) FDA has released a “Guidance for Industry and FDA Staff/FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions” which provides guidance for the industry and the FDA

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staff on the acceptance of results generated from foreign clinical studies; and (ii) the ICH guideline “Ethnic Factors in the Acceptability of Foreign Clinical Data E5 (R1)” which supports the use of foreign clinical data as a basis to support the approval of an IND application in a new jurisdiction, without the need to repeat the entire clinical drug development program in the new jurisdiction. For more details, please refer to the analysis in the paragraphs headed “– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Clinical Development Plan” in this section.

Licenses, Rights and Obligations

As we internally discovered and developed Y150, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of Y150 are as follows:

- We filed the IND application for Y150 for rrMM with the NMPA on November 17, 2020 and received the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials of Y150 for rrMM on January 18, 2021.
- We filed the IND application for Y150 for rrMM with the FDA on July 12, 2020 and received the IND approval for Y150 for rrMM from FDA on August 12, 2020.

We had not received any regulatory agency’s concerns or objections to our clinical development plans or any ongoing clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for Y150.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y150 SUCCESSFULLY.

Y2019 (RBD-dimer Subunit SARS-CoV-2 Vaccine)

Y2019 is a recombinant receptor-binding domain (RBD)-dimer subunit SARS-CoV-2 vaccine candidate for COVID-19.

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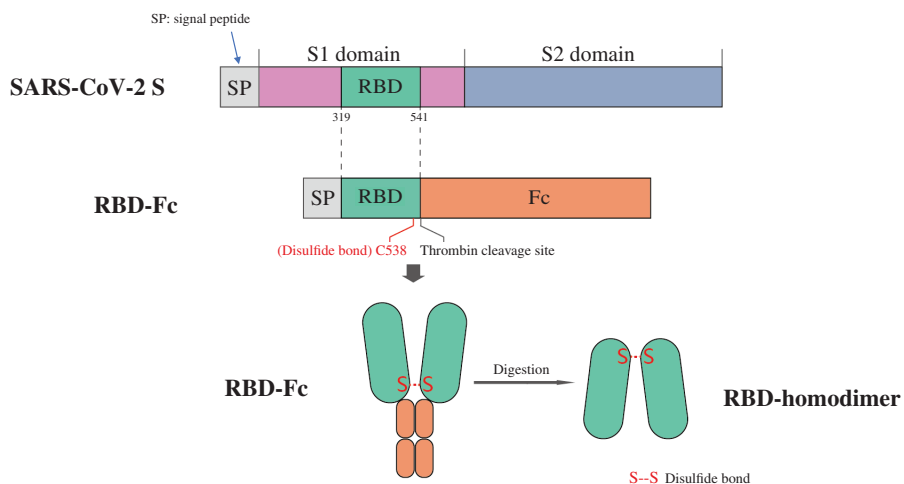
We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluated the safety and tolerability of Y2019 in healthy adults aged 18 years or older, and have obtained satisfactory 7-day and 90-day safety data post immunization. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

Mechanism of Action

The main target for vaccine development for SARS-CoV-2 is the spike (S) protein of the virus, responsible for attachment and cell entry via the cellular receptor human ACE2. Therefore, the goal for all COVID-19 vaccines is to induce high titers of neutralizing antibodies to the S protein to reduce the incidences of infection.

Y2019 consists of an RBD homodimer protein and an aluminum hydroxide adjuvant (AL). RBD is the core region of the SARS-CoV-2 S protein that binds to the receptor, human angiotensin-converting enzyme II (hACE2) on the surface of the host cells and mediates the viral invasion process. In the development of RBD homodimers, the RBD of the S protein was fused with the Fc fragment of immunoglobulin G (IgG) to produce RBD dimers with an Fc tag and the Fc fragment was then removed through thrombin digestion and repeated affinity chromatography to obtain the desired stable RBD homodimers. Adjuvants are pharmacological or immunological substances that can be added to a specific protein in a vaccine to help boost the immune response triggered by the vaccine.

The following diagram illustrates the structure of Y2019:

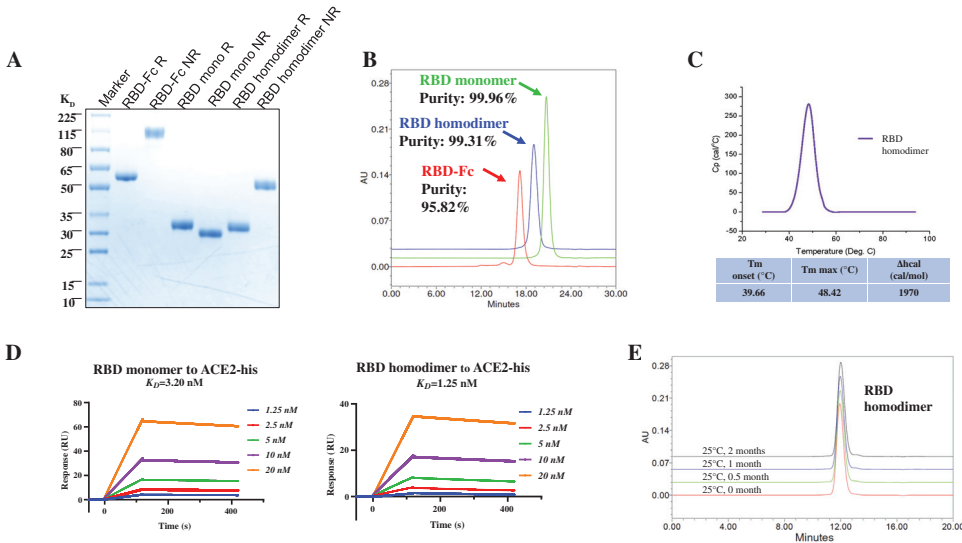


Source: Company data

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As shown below, RBD homodimer has disulfide bonds between both RBD monomers. The purification process meets the medicinal standard of high purity of RBD homodimer. The thermal stability of the RBD homodimer is good at room temperature. The affinity (K_D) of RBD homodimer to hACE2 was 1.25 nM, which is slightly better than the K_D of the monomer RBD (3.20 nM).

The RBD-homodimer showed high purity, a high affinity for hACE2, and good stability



Source: Company data

Market Opportunities and Competition

COVID-19 is associated with high transmission rates and, without adequate and effective treatment, a significant number of patients experience respiratory distress, which threatens to overwhelm global healthcare capacity.

According to the CDE and WHO websites, as of the Latest Practicable Date, 15 COVID-19 vaccines had received marketing approvals in the PRC, consisting of five inactivated vaccines, three recombinant adenovirus viral vector-based, six recombinant subunit protein vaccines and one mRNA vaccine. As of the same date, 32 clinical-stage COVID-19 pipeline candidates in the PRC were being developed, including nine using the recombinant subunit protein route.

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The chart below illustrates the marketed recombinant subunit protein COVID-19 vaccines under development in China as of the Latest Practicable Date:

China Marketed Products				
Product	Company	Medicine	Indication	Approval Time
智克威得	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd	Recombinant Subunit Protein Vaccine(CHO Cell)	COVID-19	2022/3/1
麗康 V-01	Lizhu Pharmaceutical Group Co., JoincarePharmaceutical Group Industry Co., Ltd.	Recombinant Subunit Protein Vaccine (CHO Cell)	COVID-19	2022/9/14
SCTV01C	Sinocelltech Group Limited	Recombinant Subunit Protein Vaccine	COVID-19	2022/12/4 (for emergency use)
威克欣	WestVac Biopharma Co.,Ltd, West China Hospital of Sichuan University	Recombinant Subunit Protein Vaccine (Sf9 Cell)	COVID-19	2022/12/2 (for emergency use)
SCB-2019	Sichuan Clover Biopharmaceuticals Co., Ltd., GlaxoSmithKline Pharmaceuticals	Recombinant Subunit Protein Vaccine (CHO Cell)	COVID-19	2022/12/5 (for emergency use)

Source: Annual Reports of Listed Medical Companies, NMPA, CDE, Frost & Sullivan Analysis

- (1) “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

However, the yields of these vaccines are still too low to meet the worldwide need. For details, please refer to the paragraphs headed “Industry Overview – China’s COVID-19 Vaccine Market” in this document.

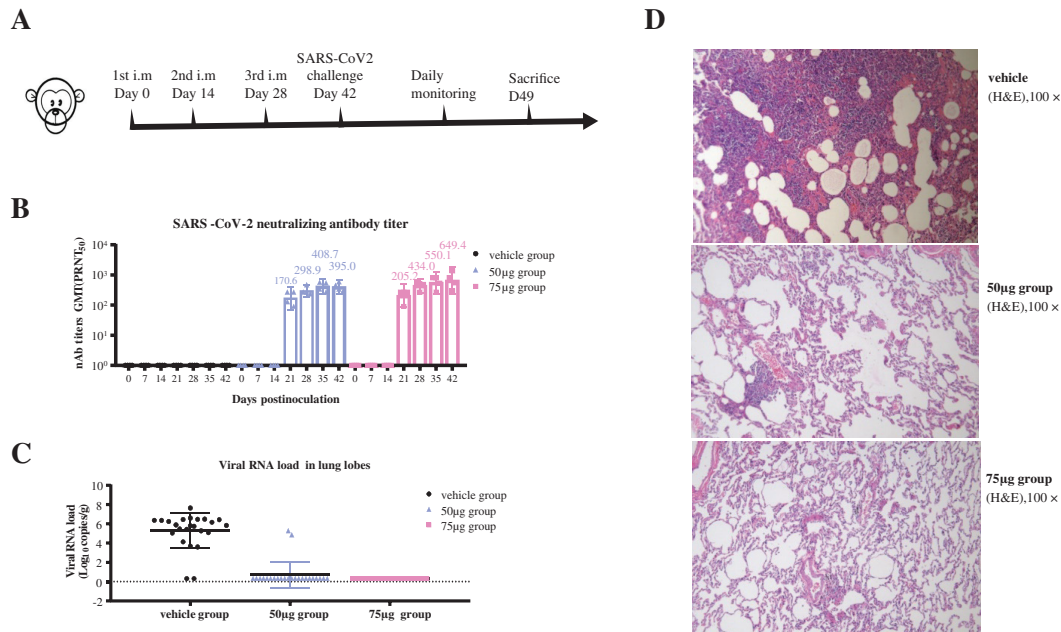
Competitive Advantages

Encouraging immunogenicity and efficacy in infection prevention in vivo

Based on our pre-clinical studies, Y2019 can induce high-level immune responses *in vivo* and prevent SARS-CoV-2 infection in non-human primates.

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Y2019 vaccine protected rhesus monkeys from pneumonia caused by SARS-CoV-2 infection



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In pre-clinical studies, we performed an *in vivo* safety evaluation of Y2019. No material changes associated with Y2019 vaccination were observed in rhesus macaques (RMs) after intramuscular injection at the doses of 50µg and 150µg RBD proteins, indicating that the Y2019 vaccination has no obvious effects on cardiovascular and respiratory systems of RMs.

Highly stable

The favorable stability profile of the Y2019 makes it suitable for storage and transportation. The results of the stability tests show that Y2019 remains stable for at least 30 days at room temperature and for at least six months in refrigerated conditions, making it suitable for long-term storage and long-distance transportation.

Summary of Clinical Trial Results

We initiated a Phase Ia clinical trial of Y2019 in China in April 2022 and have obtained satisfactory seven-day and 90-day safety data post immunization. We completed this Phase Ia clinical trial in August 2022. We expect to complete the follow-up site visit for all enrolled subjects in January 2024.

Trial design

This is a randomized, double-blinded, placebo-controlled Phase Ia clinical trial of Y2019 in China. We plan to enroll 100 healthy subjects aged 18 years or older, including 50 healthy subjects aged between 18 to 59 years old (adult subjects) and 50 healthy subjects aged 60 years or older (elderly subjects). Each subject will receive one dose intramuscular injection on day 0, day 21 and day 42 in the deltoid muscle of the upper arm. The subjects will be randomized into four groups, as illustrated below:

Age Group	Dose Level	Test Vaccine Group Subjects	Placebo Group Subjects	Subtotal	Total
Adult subjects	25µg/0.25mL (Low-dose group)	20	5	50	100
	50µg/0.5mL (High-dose group)	20	5		
Elderly subjects	25µg/0.25mL (Low-dose group)	20	5	50	
	50µg/0.5mL (High-dose group)	20	5		

Source: Company data

The primary objectives of this clinical trial are to evaluate the safety and tolerability of different doses of Y2019 in healthy people aged 18 years or older. The secondary objective of this clinical trial is to evaluate the immunogenicity of different doses of Y2019 in healthy people aged 18 years or older. The primary endpoint is the occurrence of AEs within seven days after injection of each dose of Y2019.

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Trial status

We commenced this Phase Ia clinical trial in April 2022 and completed this trial in August 2022. All of the 100 healthy subjects were enrolled in the clinical trial and all three doses of vaccination of Y2019 were completed. We have completed the three-month preliminary evaluation of the safety and efficacy of Y2019 and obtained certain data for the evaluation of the immunogenicity of live virus neutralizing antibodies. We will conduct a 14-month follow-up site visit for each subject and expect to complete such follow-up site visit in January 2024.

Safety results

The safety results indicate that Y2019 is generally safe and well tolerated. As of June 27, 2022, most of the Adverse Drug Reactions (ADRs) were Grade 1 or Grade 2 ADRs. The observed incidences of ADRs mainly included solicited local ADRs, such as pain, swelling, induration and pruritus, and solicited systemic ADRs, such as fever and fatigue. Fourteen incidences of Grade 3 or above ADRs were observed. The incidence rate of Grade 3 or above ADRs in the high-dose and low-dose groups was 7.5% (3 subjects, 9 incidences) and 7.5% (3 subjects, 5 incidences), respectively. The symptoms were:

- swelling at the site of inoculation, high dose (7.5%, 3 incidences) and low dose group (7.5%, 3 incidences)
- induration at the inoculation site was observed in high dose (5.0%, 2 incidences) and low dose group (2.5%, 1 incidence)
- pruritus at the inoculation site, high dose (2.5%, 1 incidence)
- redness at the inoculation site was observed in high dose (5.0%, 2 incidences) and low dose group (2.5%, 1 incidence)
- rash at the site of inoculation, high dose (2.5%, 1 incidence)

Observations of ADRs in vaccine clinical trials adhere to stricter standards compared to observations of AEs in drug clinical trials. The relevant standards clearly outline the solicited ADRs that must be observed in vaccine clinical trials. Specifically, the standards list solicited local ADRs, such as swelling and pruritus, and solicited systemic ADRs, such as fever and fatigue, that must be observed. These milder reactions are often not considered as AEs in drug clinical trials. As such, the ADR rate in vaccine clinical trials should not be compared to the AE rate in drug clinical trials. As illustrated above, Grade 3 or above ADRs of Y2019 mainly include tolerable syndromes such as swelling, induration or pruritus at the site of inoculation. The Grade 3 or above ADR rate in the Phase Ia clinical trial of Y2019 is comparable to those of the COVID-19 vaccines approved in China.

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Immunogenicity evaluation results

The results of immunogenicity of live virus neutralizing antibodies showed that the serum conversion rate in the low-dose groups (25µg/0.25mL/dose of Y2019) was 100% (4-fold increase of neutralizing antibody) on day 7 and day 30 post immunizations. The serum conversion rate of live virus neutralizing antibodies in the high-dose groups (50µg/0.5mL/dose of Y2019) reached 95% on day 7 and day 30 post immunizations.

The Y2019 vaccine-induced antibodies, as measured by the geometric mean titer (GMT), exhibit a temporal dependence. In a virus neutralization assay, the GMT reached its peak (109.2) 30 days post-final vaccination. Analysis of the geometric mean increment (GMI) reveals a consistent trend of temporal dependence in the Y2019 vaccine-induced antibodies. The GMI reached its peak (45.157) 30 days post-final vaccination in the virus neutralization assay.

Clinical Development Plan

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 and obtained ethical committee approval for the Phase IIa clinical trial. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

Licenses, Rights and Obligations

We have entered into an agreement to collaborate with the Wuhan Institute of Virology, Chinese Academy of Sciences (WIV) in the research and development of Y2019. For more details, please refer to the paragraphs headed “– Collaboration Agreements – Collaboration with WIV” in this section.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of Y2019 are as follows:

- We filed IND application for Y2019 with the NMPA and submitted the application documents on a rolling basis from January 8, 2021 to October 26, 2021 and received an umbrella IND approval from the NMPA for the Phase Ia, IIa, IIIa clinical trials of Y2019 for adults and Phase Ib, Phase IIb, Phase IIIb clinical trials of Y2019 for children and adolescent aged from 3 to 17 on December 10, 2021.

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- We submitted a consultation to the CDE regarding the Phase IIa clinical trial for Y2019 on April 21, 2022, and received a response from the CDE on July 7, 2022, accepting our protocol for the Phase IIa clinical trial and recommending that in the Phase IIa clinical trial, (1) we clearly define the primary immunogenic markers as the neutralizing antibody levels against the current prevalent strains of live viruses, particularly Omicron sub-variants; (2) we conduct a comparison of (a) antibody level against VOCs in the experimental group and against ancestral strain of virus in the control group and (b) antibody levels against VOCs in both the experimental group and the control group post-immunization. These recommendations by the CDE reflect their recognition of the ability of Y2019 to resist mutating VOCs.
- In addition to the above material communications with the relevant competent authorities, we also obtained the ethic committee approval to proceed with the Phase IIa clinical trial of Y2019 in healthy people aged 18 years or older in July 2022. According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), each phase of clinical drug trials shall be examined and approved by the ethics committee before being carried out.

We had not received any regulatory agency’s concerns or objections to our clinical development plans or any completed or ongoing clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for Y2019.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y2019 SUCCESSFULLY.

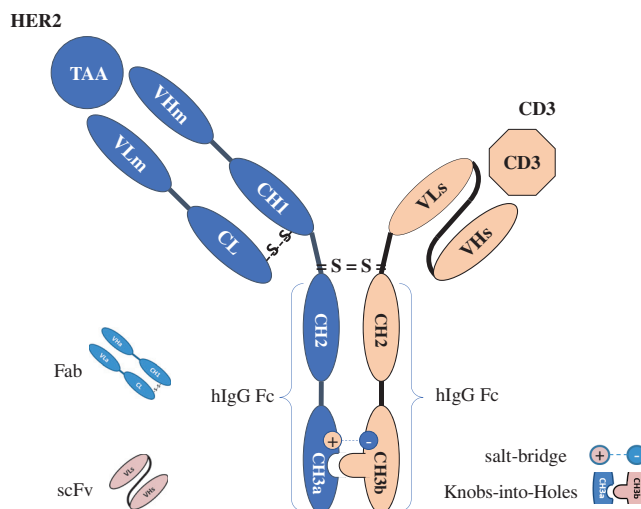
M802 (HER2 × CD3 BsAb)

M802 is a HER2 × CD3 BsAb. We completed a Phase I clinical trial of M802 for patients with HER2-positive solid tumor in China in May 2022. We will consider exploring potential out-licensing opportunities of M802 in the global market.

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Mechanism of Action

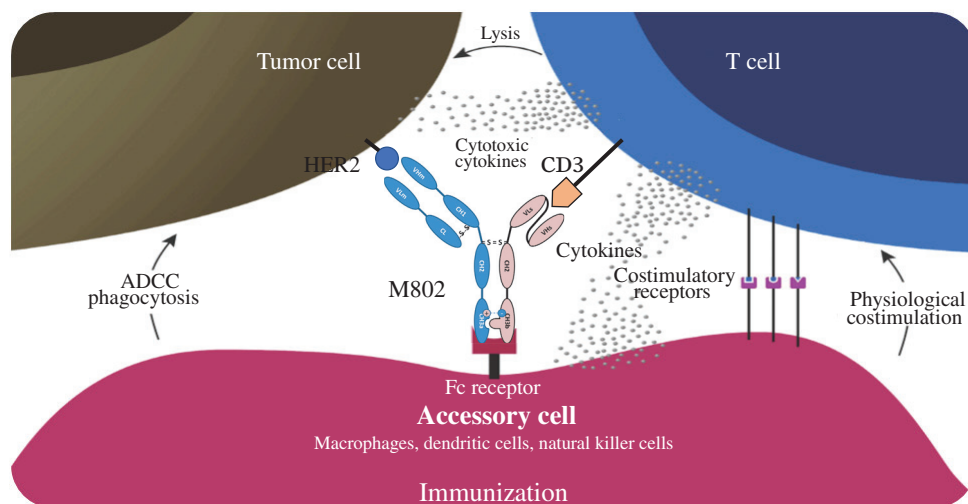
M802 is a recombinant anti-HER2 and anti-CD3 humanized BsAb that consists of a monovalent unit specifically binds to HER2 and a single chain unit which binds to CD3. The monovalent unit consists of Fab and Fc1, and the single chain unit consists of scFv and Fc2, where the Fc1 and Fc2 are from hIgG1 and mutated to form salt-bridge and KIH. The following diagram illustrates the structure of M802:



Source: Company data

HER2 plays an important role in cell proliferation, survival, differentiation, angiogenesis, cellular migration, metastatic growth, and invasion of cancer cells. Amplification of the HER2 gene or overexpression of the HER2 protein plays an important role in the development of malignant cancers. With the affinity of its monovalent unit to HER2, M802 can preferentially bind to HER2-positive tumor cells. It regulates the tumorigenesis signal pathways of tumor cells, which inhibits the proliferation and promotes the apoptosis in HER2-positive tumor cells. By binding to CD3 through its single chain unit, M802 can recruit and redirect T cells to target HER2-positive tumor cells, and further activate T cells to kill the tumor cells.

The following diagram illustrates the mechanism of actions of M802:



BUSINESS

Market Opportunities and Competition

HER2 overexpression is prevalent in many cancer types, such as breast cancer, gastric cancer, bladder cancer, pancreatic cancer and ovarian cancer. The incidence of breast cancer, gastric cancer, bladder cancer, pancreatic cancer and ovarian cancer in China reached approximately 336.3 thousand, 483.9 thousand, 88.6 thousand, 115.9 thousand and 56.2 thousand in 2021, respectively, and is expected to increase to approximately 372.4 thousand, 622.4 thousand, 117.6 thousand, 155.8 thousand and 62.7 thousand in 2030, respectively.

HER2 antibodies, such as Trastuzumab, have been used as the standard treatment for HER2-positive breast cancer and gastric cancer in combination with chemotherapy. Despite the current treatment options, there is a huge need for treatment of HER2-positive solid tumors, since patients face multiple problems, such as limited treatment options, high recurrence rates, and resistance to current treatment. Patients who have developed progression subsequently have very limited treatment options.

Moreover, according to relevant research paper published on *Journal of Practical Oncology*, patients with HER2-low expression do not respond to HER2 antibodies in general. Although HER2 antibody-drug conjugates (ADCs) are shown to be active in certain HER2-low expressing tumors in clinical trials, they are often associated with severe adverse effects, such as interstitial lung disease, and can sometimes be fatal. In addition, Trastuzumab (trade name Herceptin), a recombinant humanized anti-HER2 mAb developed by Roche, was approved by the FDA for the treatment of HER2-positive advanced breast cancer. However, approximately 70% of patients develop resistance to Herceptin, and some patients present with primary resistance. This suggests a clear need to develop novel therapeutics with a better efficacy-safety balance for patients with HER2-low expressing cancers and Trastuzumab-resistant cancers.

HER2 is an emerging target for cancer treatment. As of the Latest Practicable Date, there were ten HER2-targeted BsAb pipelines under clinical development globally (excluding China), and 13 HER2-targeted BsAb pipelines under clinical development in China. The development of HER2 × CD3 BsAbs represents an emerging trend. As of the Latest Practicable Date, there were four HER2 × CD3 BsAbs under clinical development globally, including M802, RG6194, EX 101 Injection and AMX 818, as illustrated in the table below:

Global Pipeline							
Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date ⁽¹⁾
Runitomotamab (RG6194)	Genentech, Inc.	HER2, CD3	BsAb	Advanced or Metastatic HER2-Expressing Cancers	Global	I	2018/2/27
M802	the Company	HER2, CD3	BsAb	Advanced HER2-Expressing Solid Tumors	Global China	FDA IND Approval I	\ 2018/7/26
EX101 Injection	Guangzhou AI Simai Biomedical Technology Co., Ltd.	HER2, CD3	BsAb	HER2-positive advanced solid tumors	China	I	2021/09/15
AMX 818	Amunix Pharmaceuticals	HER2, CD3	BsAb	Locally Advanced or Metastatic HER2-Expressing Cancers	Global	I	2022/5/2

Source: NMPA, CDE, ClinicalTrials.gov, FDA, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

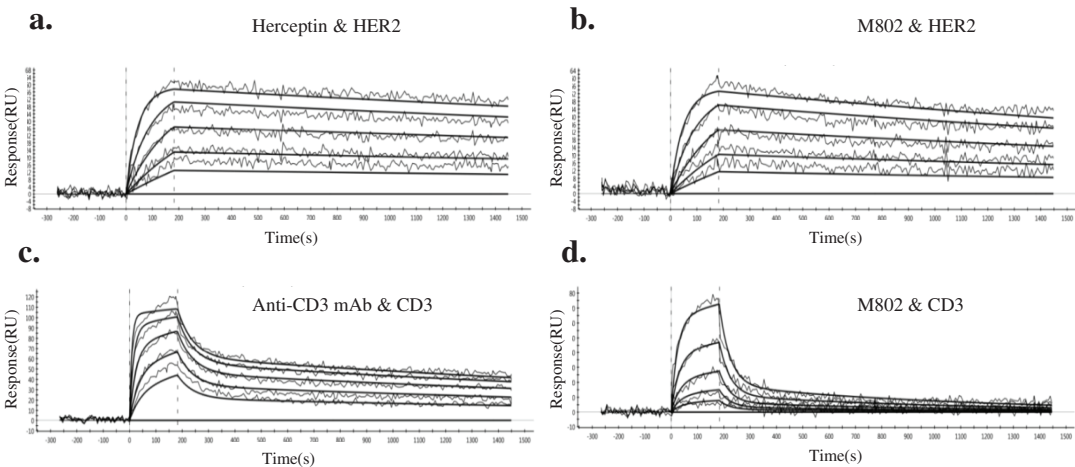
BUSINESS

Competitive Advantages

Well-designed structure to target both HER2 and CD3

Compared with monospecific antibodies, the ability to bind two different antigens or epitopes simultaneously gives BsAbs potential advantages by blocking different signaling pathways. The single chain of M802 binds to CD3 and thus can recruit T cells to target HER2-positive tumor cells and induce HER2-dependent T cell activation and cytokine release.

The affinity of M802 for HER2 is high and for CD3 is moderate



Affinity measurements of antibodies

	k_a , 1/Ms	k_d , 1/s	K_D , M
M802 and HER2 interaction	(4.29±0.17) E+05	(2.48±0.15)E-04	(5.78±0.12)E-10
Herceptin and HER2 interaction	(1.12±0.035) E+06	(1.27±0.23)E-04	(1.14±0.23)E-10
M802 and CD3 interaction	(3.45±0.191) E+05	(2.45±0.18)E-02	(7.12±0.91)E-08
Anti-CD3 mAb and CD3 interaction	(1.07±0.072) E+07	(1.31±0.19)E-02	(1.23±0.18)E-09

The association rate constant (k_a) and the dissociation rate constant (k_d) were measured with PriteOn. The equilibrium dissociation constant K_D was calculated as $K_D = K_d/K_a$.

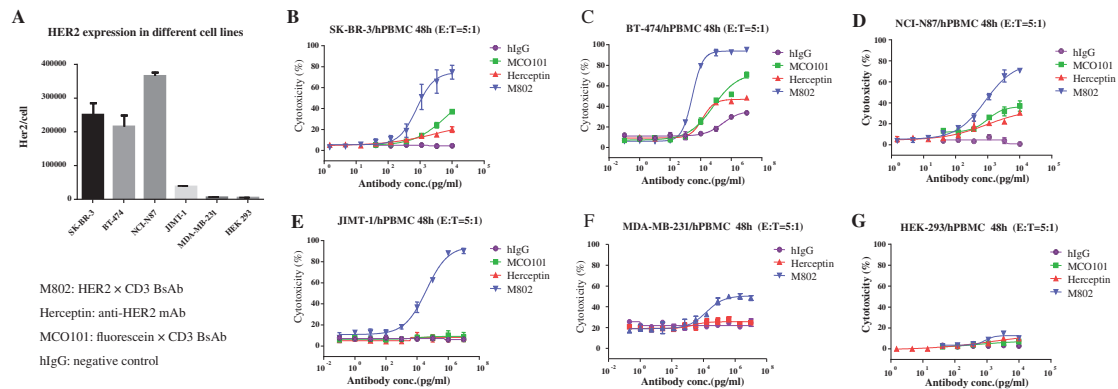
Source: Company data and published in “Yu et al. Journal of Experimental & Clinical Cancer Research (2019) 38:355”

BUSINESS

Potent anti-tumor effect

Our experiments indicate that M802 exhibits potent antitumor efficacy *in vitro* and *in vivo*. Our *in vitro* experiments suggest that M802 have remarkable cytotoxic effects against HER2-positive tumor cells, including certain Herceptin-resistant tumor cells. M802 also shows an obvious dose-dependent effect on growth inhibition of human breast cancer cells and promotes apoptosis in certain human breast cancer cells. Furthermore, M802 displays significant cytotoxicity to some Herceptin-resistant breast cancer cells (JIMT-1, MDA-MB-231).

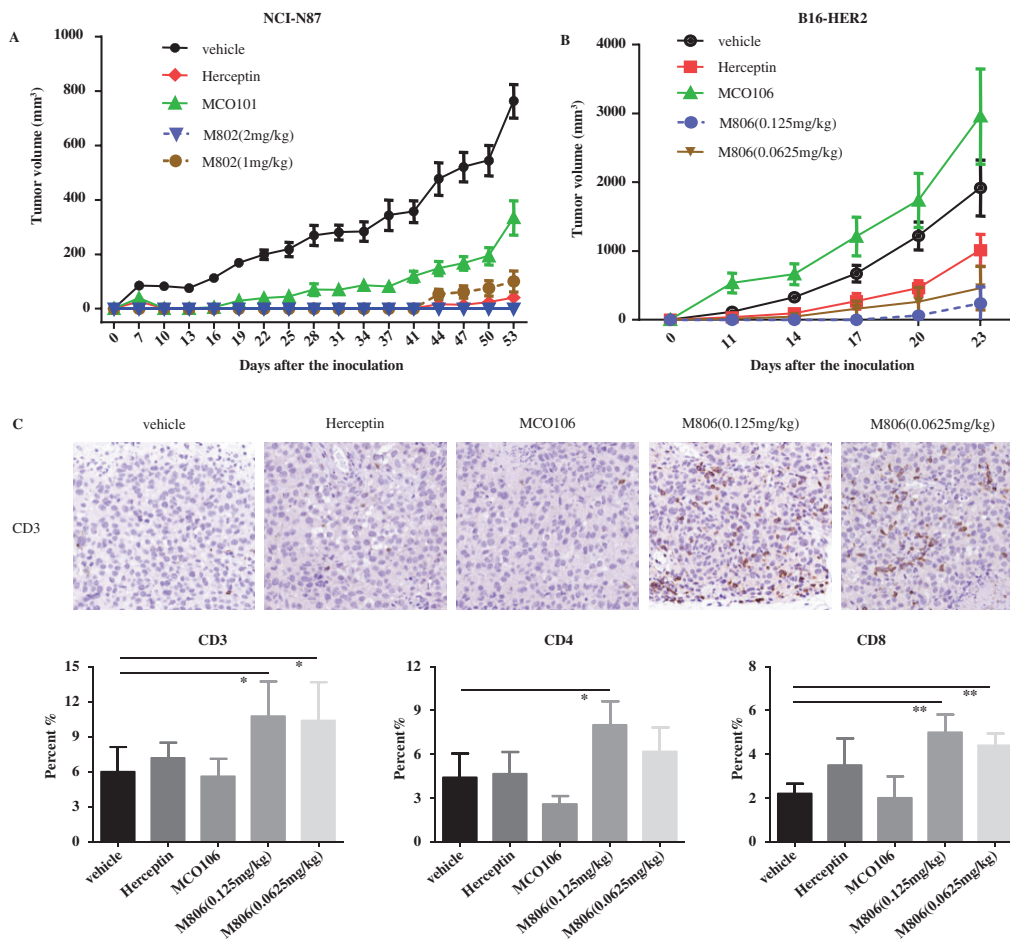
M802-mediated cytotoxicity to various target cells with different HER2 expression levels



Source: Company data and published in “Yu et al. Journal of Experimental & Clinical Cancer Research (2019) 38:355”

BUSINESS

In the animal models, M802 and M806 exhibited superior efficacy on inhibition of human gastric cancer (NCI-N87) and mouse melanoma (B16-HER2)



Source: Company data and published in “Yu et al. Journal of Experimental & Clinical Cancer Research (2019) 38:355”

As shown above, M802 exhibits superior efficacy on inhibition of human gastric cancer cells (NCI-N87) in NOD/SCID mice compared with control antibodies (as shown in A above). BsAb M806 targets human HER2 and murine CD3 on immunocompetent C57BL/6 mice. The results showed that M806 (0.125 mg/kg and 0.0625 mg/kg) significantly inhibited the growth of B16-HER2 tumors *in vivo* (as shown in B above) and recruited T lymphocytes to tumor tissues (as shown in C above). MCO101 and MCO106 are human and murine CD3 isotypes, respectively.

Favorable safety profile

M802 binds to CD3 receptor with reduced affinity, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. In pre-clinical studies, M802 is well-tolerated and generally safe. Data obtained from the Phase I clinical trial of M802 also indicates that M802 is generally safe and well tolerated.

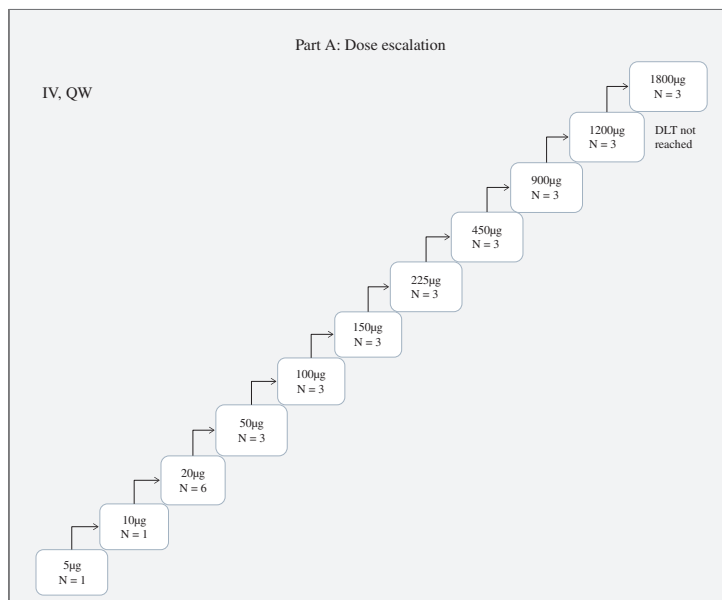
BUSINESS

Summary of Clinical Trial Results

We completed a Phase I clinical trial of M802 for patients with HER2-positive solid tumors in China. We commenced this Phase I clinical trial in September 2018. A total of 34 subjects were enrolled. We completed this clinical trial in May 2022.

This is a multi-center, open-label, dose-escalation Phase I clinical trial to evaluate the safety and tolerability of M802 in patients with HER2-positive solid tumors in China. Subjects are randomly assigned to 11 cohorts, and receive M802 on day 1, day 8, day 15 and day 22. The leading dose of M802 on day 1 ranges from 2 μ g in cohort 1 to 100 μ g in cohort 11, and starting from day 8, subjects will receive the maintenance dose of M802 ranging from 5 μ g in cohort 1 to 1,800 μ g in cohort 11. The primary endpoints are the safety and tolerability of different doses of M802 in patients with HER2-positive solid tumors, including DLT, AEs, SAEs, laboratory values, PK, and biomarkers, among others, as the basis for the RP2D. The secondary endpoints are MTD, PK, PD, immunogenicity, and efficacy parameters.

Data obtained from the Phase I clinical trial of M802 indicates that M802 is generally safe and well-tolerated. The MTD was not reached in this Phase I clinical trial. The following diagram shows the subjects enrolled in M802’s Phase I clinical trial:



Source: Company data

BUSINESS

Clinical Development Plan

We completed a Phase I clinical trial in China with M802 alone for patients with HER2-positive solid tumors.

We also received FDA IND approval for our clinical investigation for HER2 positive solid tumors in August 2019. We will consider exploring potential out-licensing opportunities of M802 in the global market.

Licenses, Rights and Obligations

As we internally discovered and developed M802, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

We had not received any regulatory agency’s concerns or objections to our clinical development plans or any completed clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for M802.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET M802 SUCCESSFULLY.

Y332 (VEGF × TGF-β BsAb)

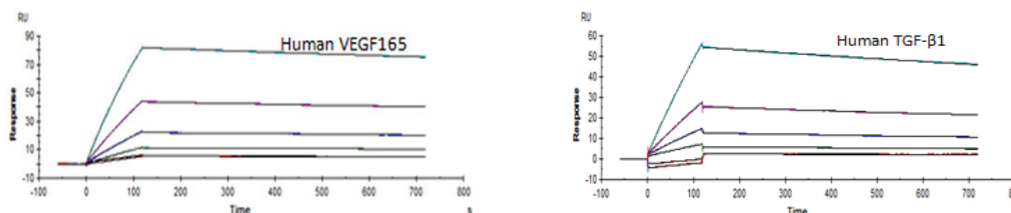
Y332 is a VEGF × TGF-β BsAb for the treatment of solid tumors. We received IND approval for Y332 for metastatic or locally advanced solid tumors in April 2023. We plan to commence a Phase I clinical trial in the third quarter of 2023 and following the completion of this Phase I clinical trial, we plan to commence a Phase Ib/II clinical trial of Y332.

BUSINESS

VEGF is a growth factor overexpressed in most solid tumors and a key driver of angiogenesis, the process that leads to the formation of new blood vessels within and around tumors. Through the blockade of VEGF/VEGF receptor signaling, Y332 inhibits the angiogenesis process, disrupting the vascular supply and starving the tumor of nutrients and oxygen. In addition to stimulating tumor angiogenesis, VEGF plays a negative role in tumor immunity via various mechanisms within the TME. TGF- β also negatively regulates multiple immune cells, facilitates the generation of CAF and stimulates the EMT process of tumor cells that restricts T cell infiltration. By simultaneously targeting VEGF and TGF- β , Y332 unlocks the therapeutical potential of blockades for both pathways, synergistically transforming the immuno-suppressive TME of cancer patients and restoring their dysregulated anti-tumor immunity. In addition, the TGF- β signaling pathway and the TGF- β -induced hypoxic TME condition promote the expression of VEGF in tumor cells. Therefore, by blocking TGF- β , Y332 downgrades tumor cells’ expression of VEGF, hence amplifying its own VEGF-inhibiting effect.

In pre-clinical studies, Y332 demonstrates high affinity to both VEGF and TGF- β , and shows noticeable anti-tumor effects, as shown in a diagram below.

High affinities of Y332 for both VEGF and TGF- β



Affinity measurements of antibodies

	k_a , 1/Ms	k_d , 1/s	K_D , M
Y332 and VEGF interaction	8.363E+05	1.476E-04	1.764E-10
Y332 and TGF- β 1 interaction	6.904E+05	4.883E-04	7.072E-10

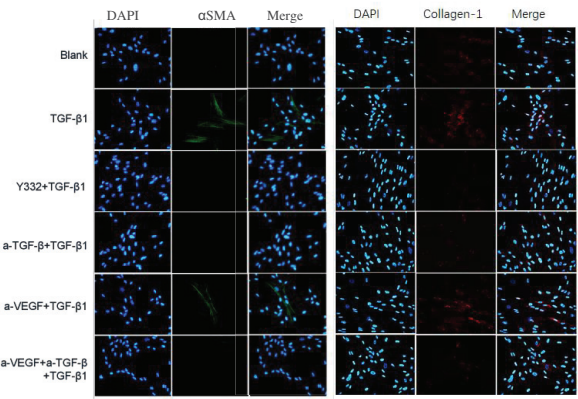
The association rate constant (k_a) and the dissociation rate constant (k_d) were measured with PriteOn in inverse seconds (1/s) or inverse milliseconds (1/Ms). The equilibrium dissociation constant K_D was calculated as $K_D = K_d/K_a$, measured in molar (M).

Source: Company data

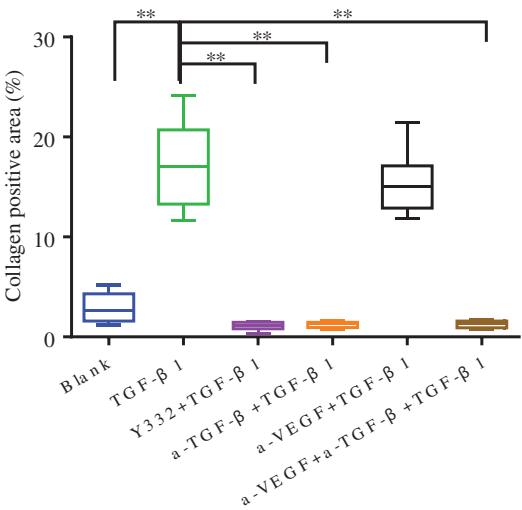
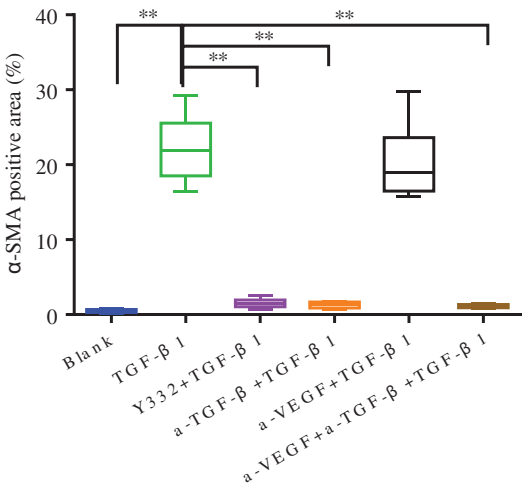
BUSINESS

As shown in the diagram below, Y332 inhibits TGF-β1-induced cancer-associated fibroblasts:

Y332 inhibits TGF-β1-induced cancer-associated fibroblasts (CAFs) activation



Note: Both αSMA and Collagen-1 are biomarkers of fibroblasts; **: p<0.01



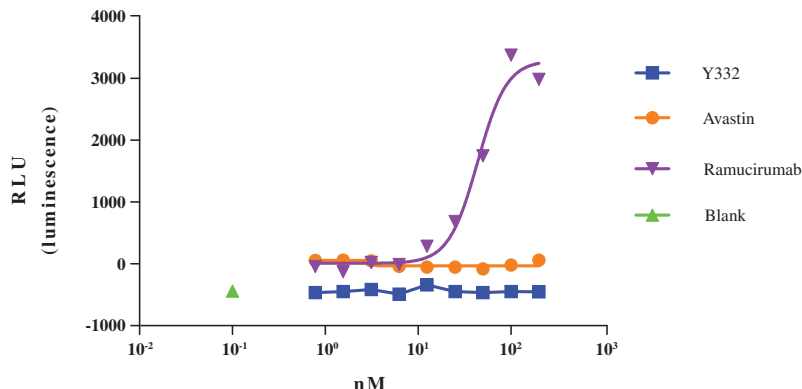
Source: Company data

BUSINESS

As shown in the diagram below, the Fc of Y332 is modified to remove ADCC effects:

The Fc of Y332 is modified to remove ADCC function

(Jurkat - FcγRIIIα : HUVEC = 3:1)

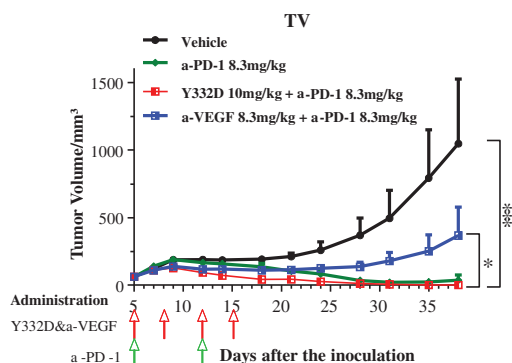


Source: Company data

Y332 could also be used in combination of immune checkpoint inhibitors to deliver an enhanced anti-tumor effect. As shown in the diagram below, in the EMT-6-hPD-L1 orthotopic tumor model (TV≈100mm³ at the time of first dose), the efficacy of the Y332D, a murine surrogate of Y332, in combination with an anti-PD-1 antibody (CR: 100%) is better than that of an anti-VEGF antibody in combination with an anti-PD-1 antibody (CR: 14.3%) and the anti-PD-1 monotherapy (CR: 85.7%).

Breast cancer EMT-6-hPD-L1 orthotopic model

Significant anti-tumor efficacy of Y332D + anti-PD-1 combination



Y332D: Y332 surrogate, anti-murine VEGF and TGF-β

EMT-6-hPD-L1: mouse breast cancer cell

The mean tumor volume at the time of the first dose was 100mm³

*: p<0.05

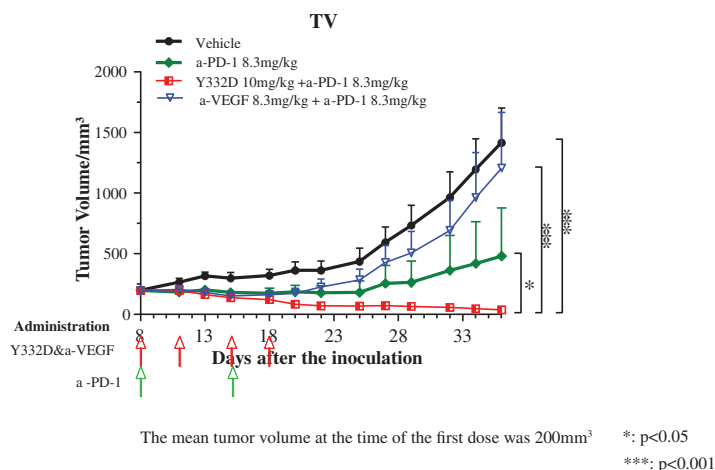
***: p<0.001

Source: Company data

BUSINESS

In the EMT-6-hPD-L1 orthotopic large tumor model ($TV \approx 200\text{mm}^3$ at the time of first dose), the efficacy of the Y332D in combination with an anti-PD-1 antibody (CR: 42.9%) is better than that of an anti-PD-1 monotherapy (CR: 28.6%) and an anti-VEGF antibody in combination with an anti-PD-1 antibody (CR: 14.3%).

Breast cancer EMT-6-hPD-L1 orthotopic model Significant anti-tumor efficacy of Y332D + anti-PD-1 combination



Source: Company data

Clinically, anti-VEGF mAbs have demonstrated an acceptable safety and efficacy profile, and anti-TGF- β -mAbs have shown little toxicity but negligible effectiveness. Leveraging the complementary and amplifying effect of both targets, Y332 could potentially be significantly more effective than the anti-VEGF or the anti-TGF- β mAbs while maintaining a comparable safety profile.

As of the Latest Practicable Date, no VEGF $\times$ TGF- β targeted drugs were marketed either globally or in China. As of the same date, one VEGF $\times$ TGF- β targeted BsAb and one PD-L1 $\times$ VEGF $\times$ TGF- β fusion protein were at clinical stage globally.

Global Pipeline

Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date ⁽¹⁾
PM8003	Biotheus Inc.	PD-L1, VEGF, TGF- β	Fusion protein	Advanced Solid Tumor	China	I	2021/7/30
ZGGS18	Suzhou Zelgen Biopharmaceuticals Co., Ltd.	VEGF, TGF- β	BsAb	Advanced Solid Tumor	Global China	FDA IND Approval I/II	\ 2022/10/20

Source: NMPA, CDE, FDA, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

BUSINESS

We internally discovered and developed Y332 and maintain the global rights to develop and commercialize this drug candidate.

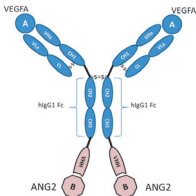
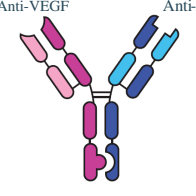
Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y332 SUCCESSFULLY.

Y400 (VEGF × ANG2 BsAb)

Y400 is an anti-VEGF and anti-angiopoietin-2 (ANG2) BsAb. The CMC studies for Y400 have been completed and the CDE approved the IND application for Y400 in April 2023.

In our *in vitro* experiment, Y400 has shown an encouraging efficacy profile. Y400 has a high concentration formulation which is an important factor for the success of such ophthalmic drugs. The diagram below lists Company data of Y400 and publicly available data of Faricimab, and is not a head-to-head study of Y400 and Faricimab.

	the Company Y400 ^[1]	Roche Faricimab ^[2]
Format		
Technology	IgG-(VHH)2, single-domain antibody	Cross-mAb, Knobs-into-Holes
Valencies	Both anti-VEGF and anti-ANG2 moieties are bivalent	Both anti-VEGF and anti-ANG2 moieties are monovalent
Concentration	140mg/ml	120mg/ml
Molecular weight	~175kDa	~145kDa
Affinity	To VEGF: 0.03nM, SPR To ANG2: 0.22nM, SPR	To VEGF: 3.5nM, SPR To ANG2: 22nM, SPR

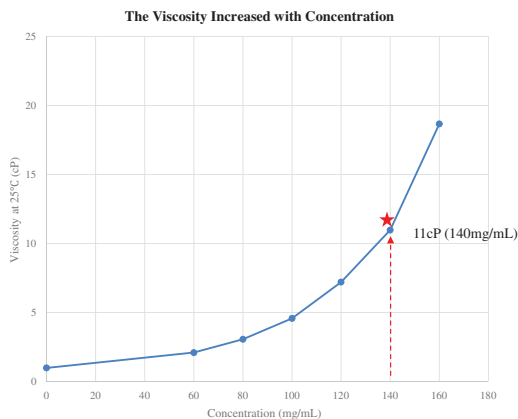
Source: (1) Company data;

(2) *EMBO Mol Med* (2016)8:1265-1288

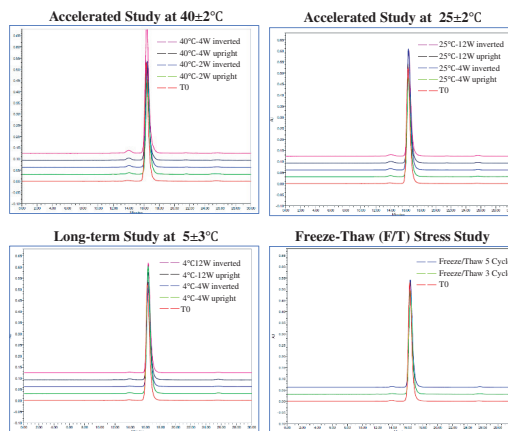
BUSINESS

Y400 is a BsAb developed based on Nano-YBODY™ technology with high-quality pharmaceutical properties, including high solubility, low viscosity, and favorable molecular stability, as shown below:

The performance of high concentration formulation of Y400 in injectability and stability



The viscosity of finished product (140mg/mL) is lower than 15 cP.
The drug product with high concentration had good injectability

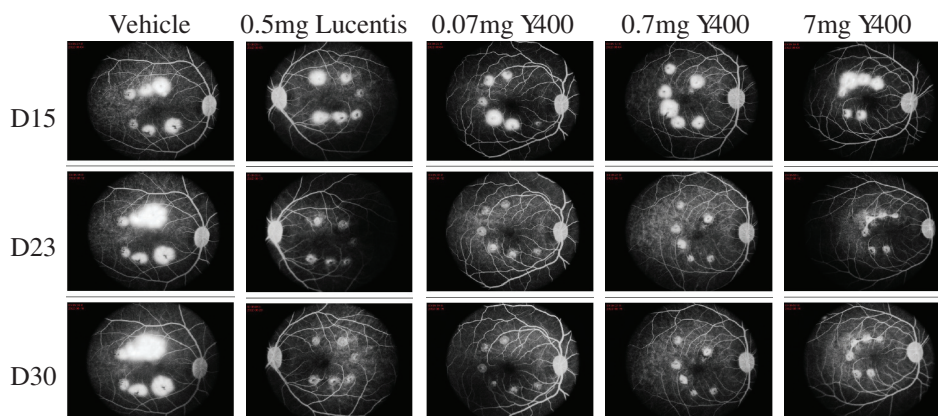


All the results remained well within the finished product specifications.
The drug product had a good stability performance

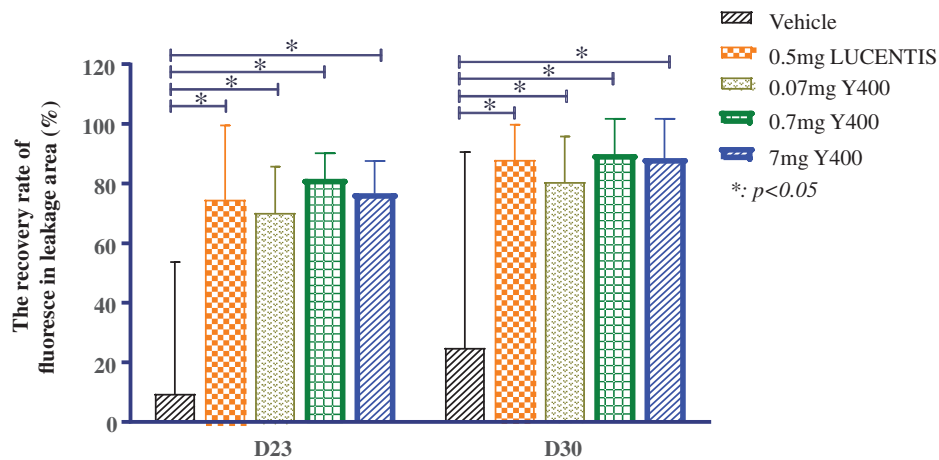
Source: Company data

As shown below, in the monkey model, the results of fluorescein fundus angiography (FFA) suggest that all doses of Y400 (0.07, 0.7, 7mg/eye) and LUCENTIS® (0.5 mg/eye) effectively inhibit the fluorescein leakage on Day 23 and Day 30, and the effects of all doses of Y400 are significant.

The recovery rate of leakage area of grade 4 lesion in Y400 groups were significantly greater than that in vehicle control group and similar to that in lucentis group



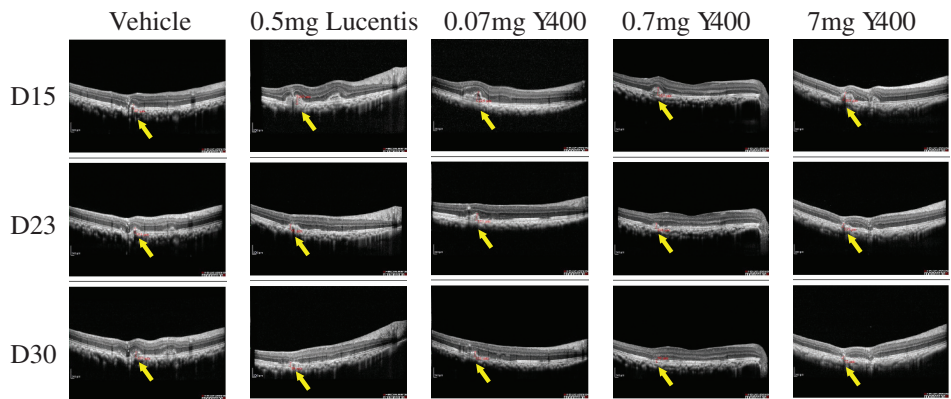
BUSINESS



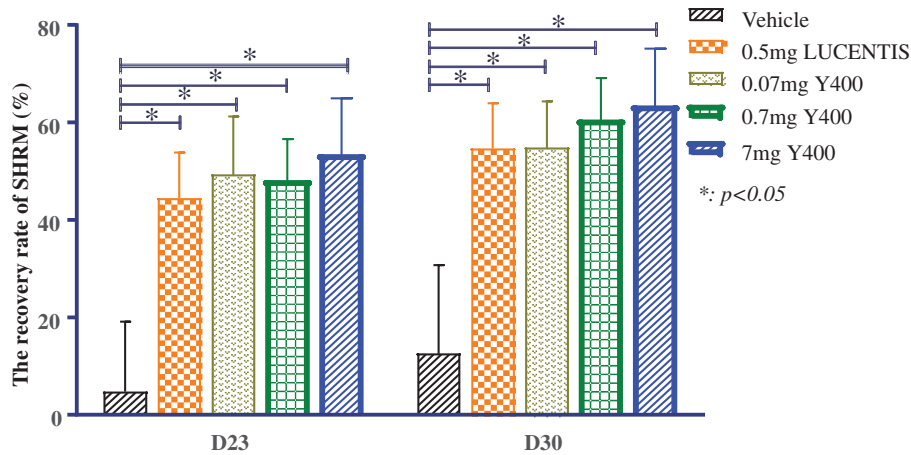
Source: Company data

As shown below, in the monkey model, the results of optical coherence tomography (OCT) suggest that all doses of Y400 (0.07, 0.7, 7 mg/eye) and LUCENTIS® (0.5 mg/eye) effectively decrease the thickness of SHRM on Day 23 and Day 30, and the effects of all doses of Y400 are significant.

The recovery rate of subretinal hyperreflective material (SHRM) of grade 4 lesion in Y400 groups were significantly greater than that in vehicle control group and similar to that in lucentis group



BUSINESS



Source: Company data

As a testament to our strong R&D capability, we have out-licensed the global rights of Y400 to Shenzhen Kangzhe Vision Pharmaceutical Development Co., Ltd., a subsidiary of China Medical System Holdings Limited (0867.HK). For further details, please refer to the paragraphs headed “– Collaboration Agreements – Collaboration with CMS Vision” in this section.

Age-related macular degeneration (AMD) is an irreversible medical condition of partial or complete vision loss caused by degenerative lesions of the retinal pigment epithelium and neuronal retina. AMD can be classified as dry (atrophic) AMD and wAMD. DME is a serious eye complication characterized by abnormal swellings (edema) in the central part of the retina caused by tiny bulges protruding from the vessel walls, leaking, or oozing fluid and blood into the retina.

In wAMD, DME and other ocular neovascularization-related diseases, abnormal blood vessel growth stimulated by vascular endothelial growth factor (VEGF) under the macula causes blood and fluid to seep into the retina. Anti-VEGF therapy improves vision in patients with wAMD, DME and other ocular neovascularization-related diseases by inhibiting the proliferation and leakage of new blood vessels. However, anti-VEGF therapy has limited ability in ablating vessel growth. Therefore, there are medical needs for drugs with multiple pro-angiogenic targets among patients who have had an incomplete response to anti-VEGF therapy. Angiopoietin-2 (ANG2) promotes vascular leakage, leading to hypotension and abnormal vascular structure. Antibodies against ANG2 inhibit neovascularization and leakage and lessen the inflammatory response.

BUSINESS

As a BsAb that simultaneously targets VEGF and ANG2, we believe Y400 has the prospect for the treatment of wAMD, DME and other ocular neovascularization-related diseases. wAMD and DME patient prevalence reached approximately 3.9 million and 7.1 million in China in 2021, accounting for approximately 1.9% and 3.5% of senior people aged at or above 65 years old in China. Y400 has a high expression level in the upstream process and the downstream process with high purity and stable quality. Leveraging our strong CMC capabilities, we would also achieve a high product purity of approximately 99% in Y400 formulation, with a product concentration of 140mg/ml.

As of the Latest Practicable Date, there were seven VEGF targeted antibody drugs or fusion proteins approved for the treatment of wAMD and DME globally (excluding China) and three approved in China. As of the same date, there were 56 and 15 VEGF targeted antibody or fusion protein drug candidates for the treatment of wAMD and DME under clinical development globally (excluding China) and in China, respectively. Among the 15 VEGF targeted antibody or fusion protein drug candidate pipelines for wAMD and DME under clinical development in China, eight were in Phase III clinical trials, two were in Phase II clinical trials and five were in Phase I clinical trials. In addition to VEGF targeted antibody or fusion proteins, there are three drug candidates in China utilizing different methods in treating wAMD and DME under clinical development, including chemical drugs and gene treatments.

Among all the VEGF targeted drugs, VEGF × ANG2 drug candidates represent an emerging trend. As of the Latest Practicable Date, there were three VEGF × ANG2 drug candidates for treating neovascular eye diseases under clinical development in China:

China Pipeline							
Product	Drug Name	Developer	Target	Drug Type	Indication	Highest Clinical Phase	First Posted Date ⁽¹⁾
Faricimab Injection	Faricimab	F. Hoffmann-La Roche Ltd	ANG2, VEGF	BsAb	DME, macular edema secondary to branch RVO, wAMD, CRVO or hemi retinal vein occlusion secondary to macular edema, polypoidal choroidal vasculopathy	III	2021/7/6
IBI324	IBI324	Innovent Biologics (Suzhou) Co. Ltd.	VEGF, ANG2	BsAb	DME	I	2022/6/17
ASKG-712	ASKG-712	Suzhou Aosaikang Biopharmaceutical Co., Ltd.	ANG2, VEGF	Fusion Protein	wAMD	I	2022/7/29

Source: NMPA, CDE, Frost & Sullivan Analysis

Abbreviations: RVO refers to retinal vein occlusion; CRVO refers to central retinal vein occlusion.

(1) “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

As Y400 received the IND approval in April 2023, it’s still at very early clinical development stage when compared to other VEGF targeted therapies and ANG2 targeted therapies, and face fierce competition for the treatment of wAMD and DME.

BUSINESS

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y400 SUCCESSFULLY.

OUR R&D PLATFORM

We believe that strong in-house research and development capabilities are critical to our success. We have built an integrated research and development platform that encompasses three main functions: drug discovery and pre-clinical development function, CMC function and clinical development function. With collaboration among such functional groups, we are able to bring our strong pipeline of innovative drugs from inception through development, manufacturing and commercialization.

We are dedicated to enhancing our pipeline by leveraging our strong in-house research and development capabilities, from early-stage drug discovery to clinical development. As of the Latest Practicable Date, our research and development team consisted of 99 employees, 46.5% of which have a master’s degree or higher and 24 are our key R&D staff. We also work with CROs to support our pre-clinical and clinical studies in China. Our research and development team members have extensive pre-clinical and clinical development experience, focusing on oncology and immunology. In 2021 and 2022, our total research and development expenses were RMB112.9 million and RMB157.3 million, respectively, and the research and development expenses attributable to our Core Product, M701, amounted to RMB9.9 million and RMB23.5 million, representing approximately 8.7% and 15.0% of the total research and development expenses for the same years, respectively. In 2021 and 2022, our total research and development expenses accounted for approximately 78.2% and 88.5% of our operating expenses (being the research and development expenses and administrative expenses) for the same years, respectively. For details about our research and development expenses in relation to M701 for different indications and the remaining drug candidates, respectively, and the explanation of fluctuations of our research and development expenses, please refer to the paragraphs headed “Financial Information – Descriptions of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Research and Development Expenses” in this document.

Our key R&D staff have an average of 12 years of relevant experience working in the biopharmaceutical industry, and remained employed during the Track Record Period and up to the Latest Practicable Date. Many of them have worked on biotechnology and/or biopharmaceutical research at renowned research institutions (such as the University of Texas M.D. Anderson Cancer Center and the Institute of Biophysics of the Chinese Academy of Science) and corporations (such as Becton, Dickinson and Company and WuXi Biologics Co., Ltd.) and have accumulated profound experience in drug discovery, pre-clinical and clinical development, process development and manufacturing, quality control and assurance, and registration management. More than 85% of our key R&D staff have a master’s degree or higher in relevant fields, including, but not limited to, medicine, cancer biology, molecular

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biology, microbiology, biotechnology, chemical technology, biochemistry and immunology. More than 90% of our key R&D staff have engaged in the projects in relation to the R&D of M701. Approximately 80% of these key R&D staff have engaged in the projects in relation to the R&D of Y332 and Y400, and approximately 60% of the key R&D staff have engaged in the projects in relation to the R&D of Y101D and Y150.

Compared to mAbs, BsAb production poses greater challenges in terms of upstream expression, downstream purification yield and product stability. We have achieved breakthroughs in the following areas through our technical accumulation and project development.

- *Expression.* The expression level of BsAbs in production is generally low. Leveraging our advanced technology platforms, we have optimized the vector construction, cell line screening and cell culture process in BsAb production and can reach an expression level of over 8.0g/L for Nano-YBODY™ molecules, which has enhanced the competitiveness of our products for industrialization.
- *Purity and yield.* Another great challenge in manufacturing BsAbs is generally low purity and yield. We are dedicated to the combination and optimization of downstream purification strategies and have developed a high-purity and high-yield purification process. The total yield of BsAbs in our purification process can reach 75%, and the purity of the drug substance can reach 99% with low levels of impurities.
- *Stability.* The stability of BsAbs poses a challenge in its production. We are able to meet stability requirements in storage and transportation of different products through substantial prescription screenings and optimizations. The final formulation products remain stable for over three years.

Drug Discovery and Pre-clinical Development

Our drug discovery and pre-clinical development function is led by Dr. Zhou Pengfei and Mr. Zhang Jing. Dr. Zhou has over 33 years of experience in the healthcare and pharmaceutical industries. He obtained a bachelor's degree in pediatrics and a master's degree in pediatric surgery (oncology) from Tongji Medical University (currently known as Tongji Medical College of Huazhong University of Science and Technology) in the PRC. He also obtained a doctorate in medicine from McMaster University in Canada. For more details about Dr. Zhou's background and credentials, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Directors – Executive Director” in this document. Mr. Zhang has relevant working experience of almost 15 years in the biopharmaceutical industry. He obtained a bachelor's degree in biotechnology from Wuhan University and a master's degree in biochemistry and molecular biology from the Graduate School of the Chinese Academy of Science (currently known as the University of Chinese Academy of Science). For more details

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about Mr. Zhang’s background and credentials, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Supervisors” in this document. As of the Latest Practicable Date, our drug discovery and pre-clinical development function consisted of 23 members.

Our drug discovery and pre-clinical development function comprises three divisions, namely, antibody engineering division, early discovery and research division and pharmacodynamics, pharmacokinetics and toxicology division.

- The antibody engineering division focuses on the discovery, sequence optimization, structure design, small preparation and early stability assessment of antibodies.
- The early discovery and research division is responsible for target research and scientific cooperation to initiate research and development projects.
- The pharmacodynamics, pharmacokinetics and toxicology division evaluates the *in vivo* efficacy and mechanisms of action of the antibodies, explores toxicity, and reviews the protocols of formal safety evaluation experiments.

Our Technology Platforms

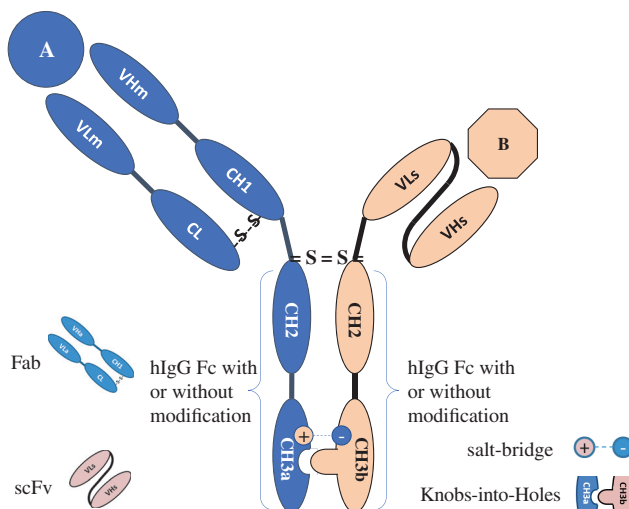
We have successfully built four platforms, including the self-developed YBODY[®], Check-BODY and Nano-YBODY[™] platform, and the UVAX[®] platform developed in collaboration with WIV. These platforms serve as an engine for our continuous endeavor to deliver new drug candidates, including potential drug candidates we may develop in the future utilizing the molecular structures and CMC processes of the platforms.

YBODY[®] Platform

YBODY[®] platform is our first in-house developed asymmetrical BsAb platform. YBODY[®] platform is an innovative BsAb platform that focuses on the development of asymmetric human IgG-like BsAbs with scFv-Fab-Fc structure. We have discovered and developed M701, M802 and Y150 based on the technologies of the YBODY[®] platform. By binding both tumor-associated antigens (TAAs) and human immune cells, molecules being developed leveraging YBODY[®] platform can recognize, inhibit and kill tumor cells. They can also stimulate human immune system, increase cytotoxicity towards tumor cells, and inhibit tumor relapse and dissemination.

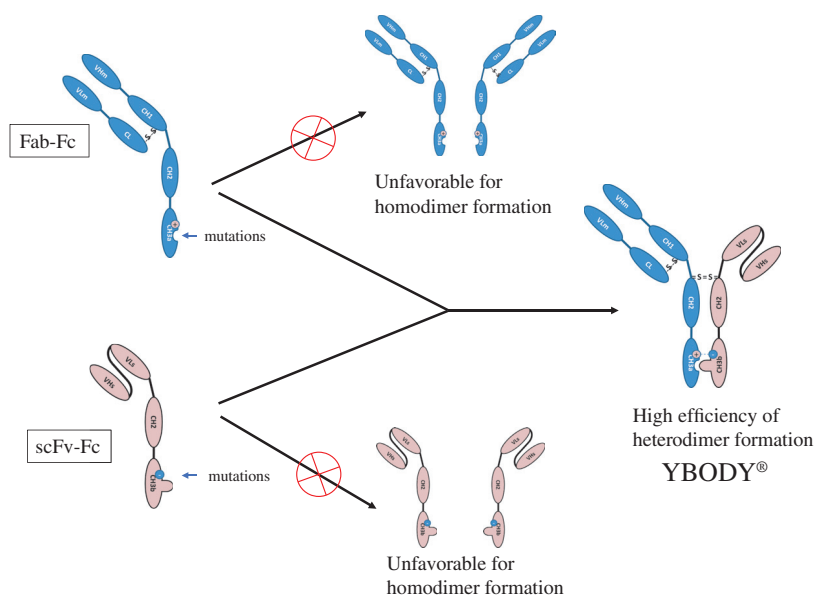
An YBODY[®] molecule is composed of three polypeptide chains, a heavy chain, a light chain, and a single chain, to form three segments, as illustrated in the diagram below. The first moiety is a Fab fragment that targets antigen A, such as TAAs. The second moiety is a scFv fragment that targets antigen B, such as immune-associated antigen. The third moiety is a Fc region with or without modification to retain or eliminate the binding to FcγRs.

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Source: Company data

As illustrated by the diagram below, with respect to the anti-TAA Fab-Fc and anti-CD3 scFv-Fc, we utilize the KIH and salt-bridge technologies in the Fc mutations to disfavor the formation of homodimers and achieve the desired heterodimeric BsAbs. The proprietary design of the scFv is also applied to avoid mispairing of the heavy chains and the light chains. Furthermore, we can easily identify the misassembled impurities of BsAbs through the asymmetry of the molecular weight and thus remove the impurities through the asymmetry of the molecular charge. The integration of these technologies ensures the favorable formation of the desired heterodimeric BsAbs in CHO cells and downstream purification of the desired YBODY[®] products by conventional chromatography.



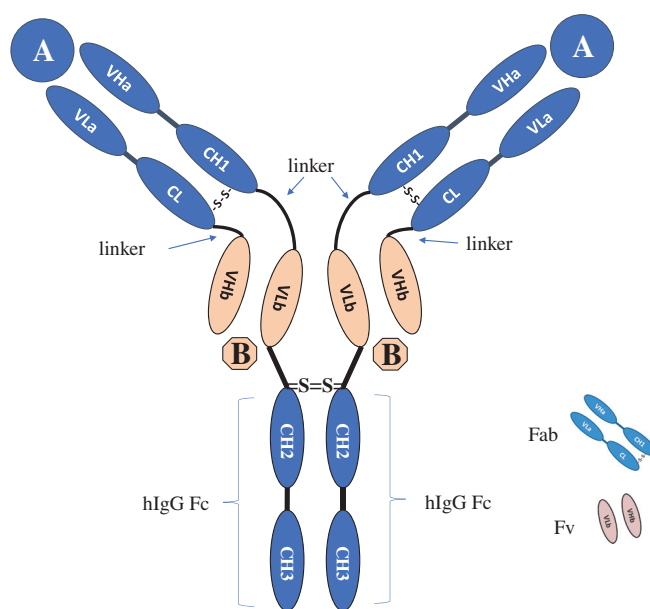
Source: Company data

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The well-designed structure of the asymmetrical BsAbs that leverages the YBODY[®] platform features moderate affinity to human immune cells, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. The misassembled impurities can be easily identified through the asymmetry of the molecular weight of the BsAbs and removed through the asymmetry of the molecular charge, which improves the efficiency of the desired dimerization and formation of YBODY[®] molecules. Based on the high performance of our well-developed CMC platform, we are able to develop BsAbs with consistent high quality in multiple batches and easily scale up the manufacturing of YBODY[®] molecules. The stability and expression level of our YBODY[®] molecules are close to those of common mAbs. Our YBODY[®] molecules were found to remain stable for over three years in the stability assessment, which is comparable to the marketed anti-CD3 BsAbs around the world.

Check-BODY Platform

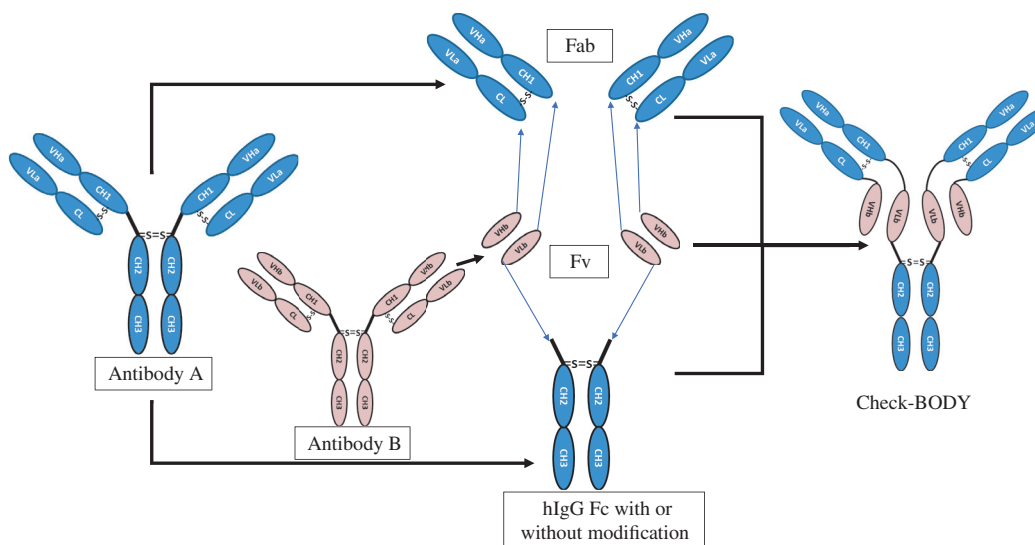
Our in-house developed Check-BODY platform is designed for the development of symmetric tetravalent BsAbs. We have discovered and developed Y101D based on the technologies of the Check-BODY platform. A Check-BODY molecule is composed of three segments, as illustrated in the diagram below: (i) two Fab fragments from antibody A to target antigen A, (ii) two variable fragments (Fv) from antibody B to target antigen B, and (iii) Fc fragments from human IgG with modification or not.



Source: Company data

We apply the genetic engineering technology to use protein linkers to connect the Fab fragments with Fv fragments and the Fc fragments, respectively, and therefore achieve the ultimate symmetric tetravalent BsAb products, the Check-BODY molecules.

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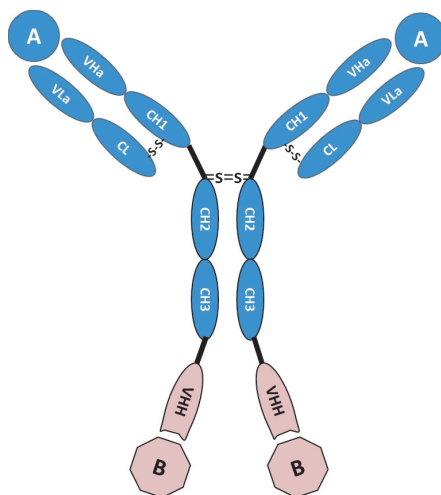


Source: Company data

Both Fab and Fv moieties of a Check-BODY molecule show high affinity to the respective targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like mAbs and therefore is easier to achieve. We are able to develop Check-BODY molecules with consistent high quality in multiple batches. The average expression level for Check-BODY molecules is nearly 6.0g/L in the Fed-Batch mode with the yield rate higher than 50%.

Nano-YBODY™ Platform

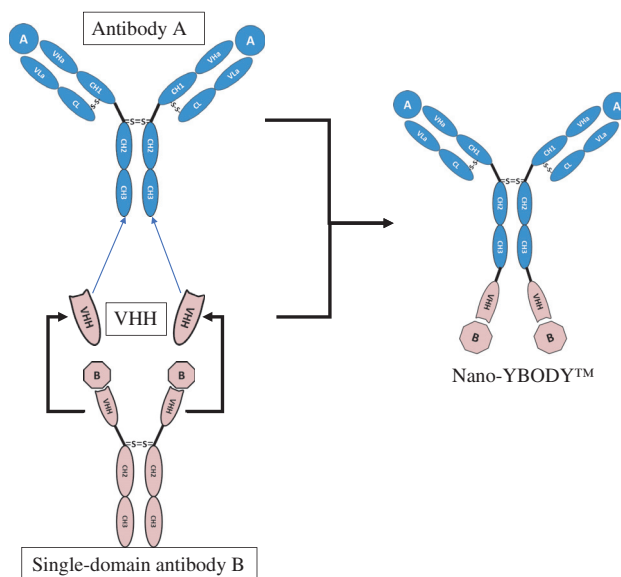
Our in-house developed Nano-YBODY™ platform is designed for the development of symmetric tetraivalent BsAbs. We have discovered Y400 and Y332 based on the technologies of the Nano-YBODY™ platform. A Nano-YBODY™ molecule is composed of the following, as illustrated in the diagram below: (i) a typical IgG antibody with two Fab moieties, and (ii) the two variable domains of a heavy chain (VHH) of a single-domain antibody (sdAb).



Source: Company data

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We apply the genetic engineering technology to use protein linkers to connect each of the two heavy chains of an IgG antibody with each of the two VHH fragments from an sdAb, as illustrated below.



Source: Company data

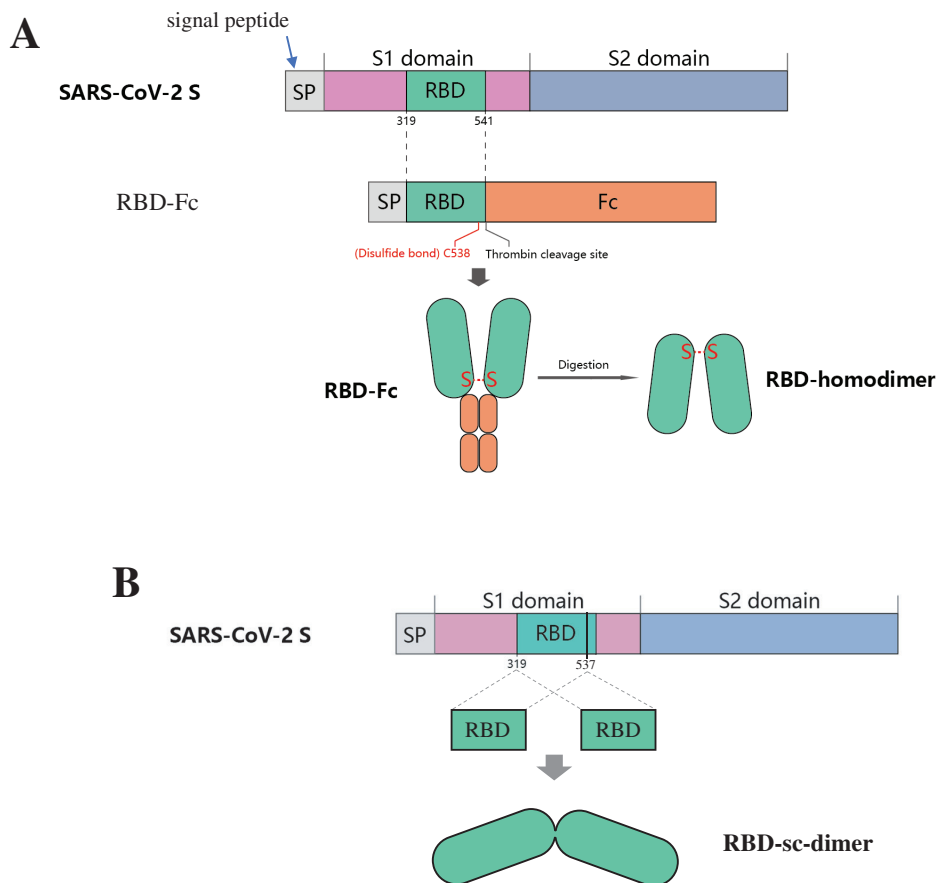
Both the Fab and the VHH moieties of a Nano-YBODY™ molecule show high affinity to the respective targets. The Nano-YBODY™ molecules have demonstrated a superior performance in expression level, purification yield, solubility, and stability. The average expression level for Nano-YBODY™ molecules is greater than 8.0g/L with recovery rate over 70%. We have developed Nano-YBODY™-based molecules at a superiorly high concentration up to 140 mg/mL for intravitreal injection with the product purity of approximately 99%.

UVAX® Platform

Our UVAX® platform, developed in collaboration with WIV, is a unique immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our proprietary BsAb engineering technologies. We utilize our UVAX® platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield CHO expression and antibody-like purification systems. The platform enables us to make significant progress in the development of coronavirus vaccine Y2019. Y2019 is a homodimerized protein, of which two RBD monomers are linked covalently by an interdomain disulfide bond at the C terminus of the RBD of the S protein. According to the design, the SARS-CoV-2 RBD gene (319–541 amino acid) is fused with the Fc gene of human IgG, and the DNA of the genes are constructed into the vector to express the RBD-Fc fusion protein. The Fc fragment of the fusion protein is then removed by thrombin digestion

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and purification to obtain the RBD homodimer protein as the immunogen of the vaccine. The structure of our RBD-homodimer is illustrated in the diagram below (A), and it is similar to the marketed vaccine ZF2001 (Zhifei Longcom) of which structure is RBD-sc-dimer (B):



Source: A, Company data and published in “Pan et al. Cell Discovery (2021) 7:82”;

B, the reference “Dai et al., 2020, Cell 182, 722–733”

Our RBD-homodimer is produced in an industry-standard CHO cell system. We have two 200L production lines and are able to produce about 40 million doses at 50µg per dose annually. The production of our RBD-homodimer can be rapidly scaled up. Moreover, based on our UVAX[®] platform, the vaccines to the VOCs for SARS-CoV-2 can be rapidly prepared within three months.

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Clinical Development

Clinical Development Team

Our clinical development team is led by Dr. Huang Shaoyi. Dr. Huang Shaoyi has relevant working experience of almost ten years in clinical research and product development. He obtained a bachelor’s degree in biotechnology and a master’s degree in microbiology from Wuhan University, and a doctorate in cancer biology from the University of Texas Health Science Center at Houston and the University of Texas M.D. Anderson Cancer Center in the United States. For more details about Dr. Huang’s background and credentials, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Senior Management” in this document. As of the Latest Practicable Date, our clinical development team consisted of 12 members.

The clinical development team is mainly responsible for clinical trial design, document preparation, trial operations (including subject enrollment), clinical data monitoring, project management, data analysis and safety management.

Clinical Trial Design and Implementation

As of the Latest Practicable Date, seven of our drugs have entered into clinical development stage. Our clinical trial design is mainly based on the characteristics of our drug candidates and the market demand, including the MOA and applicable targets of our drug candidates, the current clinical treatment status of targets and the selection of appropriate indications. We also consider the opinions of researchers and CROs engaged in the clinical trials. We take into account the target cancers of our clinical trials and select the most suitable research centers and patients to be engaged to accelerate our clinical trials as much as possible. We also maintain a good safety and efficacy profile of our drug candidates to ensure the willingness and efficiency of the subject enrollment.

All of the clinical trial designs need to be approved by the head of the clinical development team, the head of our quality center and Dr. Zhou Pengfei, our chief executive officer. Both a hard copy and an electronic version of the relevant documents are required for record. We have executed an adaptive clinical development strategy. A practical design of clinical trials, including with respect to the number of subjects to be enrolled for our clinical trials, is important to our clinical trial implementation. The number of subjects to be enrolled for our clinical trials is determined based on the anticipated trial designs, as well as various factors influencing these designs.

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The following table sets forth the methodologies for determining the number of subjects to be enrolled for different types of our clinical trials.

Our clinical trials	Methodologies applied
Single-arm Phase I/Phase Ib trials (Phase Ib portions of Phase Ib/II trials and a Phase I portion of a Phase I/II trial) of (a) M701 for MPE and solid tumor, (b) Y101D for metastatic or locally advanced solid tumors, advanced/metastatic pancreatic cancer (in combination with gemcitabine and albumin paclitaxel), HCC and other advanced solid tumors (in combination with bevacizumab), and SCLC (in combination with chemotherapy), (c) Y150 for rrMM in monotherapy and in combination with lenalidomide, and (d) Y332 for solid tumors in monotherapy and in combination therapy.	The number of subjects to be enrolled for these trials depends on: (a) the number of cohorts in the dose-escalation stage of these trials, influenced by the initial dose, expected MTD, and dose escalation gradient between cohorts, (b) the likelihood of encountering a DLT in any cohort which typically causes the enrollment of additional subjects to that cohort in the dose-escalation stage, and (c) the number of subjects for the cohort-expansion stage, dictated by the depth of insight we aim to acquire regarding the safety and preliminary efficacy of a drug candidate before proceeding to Phase II.
Controlled Phase II trial of M701 for MA and controlled Phase II portion of Phase Ib/II trial of M701 for MPE.	These trials comprise a control arm and a treatment arm each enrolling equal number of subjects, with the CDE recommending a minimum of 30 subjects to be enrolled in each arm to prevent statistical bias.

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Our clinical trials

Single-arm Phase II trials (Phase II portion of Phase I/II trial or Phase II portions of Phase Ib/II trials) of (a) M701 for solid tumor, (b) Y101D for advanced/metastatic pancreatic cancer (in combination with gemcitabine and albumin paclitaxel), HCC and other advanced solid tumors (in combination with bevacizumab), and SCLC (in combination with chemotherapy), (c) Y150 for rrMM in combination with lenalidomide, and (d) Y332 for solid tumors in combination therapy.

Controlled Phase III trials of (a) M701 for MA and MPE, and (b) Y101D for advanced/metastatic pancreatic cancer (in combination with gemcitabine and albumin paclitaxel), and HCC and other advanced solid tumors (in combination with bevacizumab).

Methodologies applied

The number of subjects to be enrolled for these trials depends on our plan to study the efficacy of our drug candidates in different tumor subtypes or different tumor cell gene expression subtypes within the same tumor indication. We typically recruit 25-30 subjects for each subtype we plan to study in these trials to minimize statistical bias. We plan to conduct subtype studies in (a) a Phase II portion of Phase I/II trial of M701 for solid tumor, (b) a Phase II portion of Phase Ib/II trial of Y101D for SCLC (in combination with chemotherapy), and (c) a Phase II portion of Phase Ib/II trial of Y150 for rrMM in combination with lenalidomide. For the Phase II trials that do not involve subtype studies, we plan to enroll 30-50 subjects each to avert statistical bias.

The estimated number of subjects to be enrolled for these trials is determined according to the statistical requirement to validate the superiority of the drug candidates in the treatment arm relative to the control arm. Statistically, the less significant the superiority of the treatment arm is compared to control arm, the greater influence random disturbances would have on this subtle advantage, and the more subjects should be enrolled to mitigate the impact of the random disturbances and to achieve statistical significance results. The requirement of CDE to enroll at least 300 subjects receiving the RP2D dose across all clinical trial phases and indications to evaluate the safety profile of a drug candidate is also considered in determining the estimated number of subjects to be enrolled for these trials.

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Our clinical trials

Single-arm Phase II/III trial of Y150 for rrMM.

Methodologies applied

For rare indications lacking effective therapies such as rrMM, the CDE does not require a minimum of 300 subjects to receive the RP2D dose before approving a drug candidate. Therefore, we plan to enroll around 200 subjects in our Phase II/III trial of Y150 for the treatment of rrMM to expedite the trial process.

We abide by the requirements of the NMPA/CDE in determining the number of subjects to be enrolled for our planned clinical trials, specifically:

- (a) The NMPA/CDE does not specify a minimum number of subjects to be enrolled in Phase I trials, Phase Ib/II trials, Phase I/II trials, or Phase II trials.
- (b) The CDE typically requires a total of no less than 300 subjects receiving the RP2D dose across all clinical trial phases and indications of a cancer drug candidate for safety evaluation before approval for marketing. We plan to enroll more subjects for our four controlled Phase III clinical trials than this minimum requirement, with an aim to meeting statistical demands to validate the superiority of the drug candidates compared to control treatment.
- (c) For rare indications lacking effective therapies, such as rrMM, the CDE does not require a minimum of 300 subjects to receive the RP2D dose before approving a drug candidate. We plan to enroll around 200 subjects in the Phase II/III trial of Y150 for the treatment of rrMM to expedite the trial process, which is in line with CDE requirements.

The expected number of subjects to be enrolled for each type of our clinical trials is in line with that of similar drug candidates in similar clinical stages developed by the industry peers in China.

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Collaboration with CROs, SMOs, CMOs/CDMOs, and Other Third Parties

In line with the practice in the pharmaceutical industry, we engage CROs, SMOs, CMOs/CDMOs and third-party research centers (i.e., hospitals and laboratory centers) to conduct and support our preclinical studies and clinical trials. We closely supervise the activities of these third party collaborators. We have selected these institutions by weighing various factors, such as their qualifications, expertise, experience, reputation, and costs.

The following table sets forth the number of CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers we engaged during the Track Record Period:

	For the years ended December 31,	
	2021	2022
CRO	28	27
SMO	12	22
CMO/CDMO	3	1
Hospital	33	37
Laboratory Center	7	13

The following table sets forth the background of our key CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers engaged by us, as well as their involvement and contributions in the research and development and clinical trials:

	Background	Involvement
CRO 1	A China-based non-clinical CRO primarily engaging in drug safety assessment	Provision of preclinical safety assessment and detection work of clinical samples
CRO 2	A China-based pharmaceutical company primarily engaging in R&D of new drug and technology	Provision of pre-clinical and clinical CRO work, including but not limited to clinical operation, medical supervision, statistics and drug alert services
SMO 1	A China-based biotechnology company primarily engaging in providing technology development, transfer and consulting services in pharmaceutical industry	Provision of SMO work, including but not limited to project approval, start-up, screening and coordination services for clinical trials in certain laboratory centers

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	Background	Involvement
SMO 2	A China-based biotechnology company primarily engaging in providing technology development, transfer and consulting services in medical and clinical medical technology industry	Provision of SMO work, including but not limited to project approval, start-up, screening and coordination services for clinical trials in certain laboratory centers
CDMO	A China-based biomedical company primarily engaging in providing one-stop services for biomacromolecules drugs	Provision of production of clinical samples
CMO	A China-based biotechnology company primarily engaging in pharmaceutical production, pharmaceutical commissioned production and medical device production	Provision of formulation production of clinical samples
Hospital	A China-based Class III-A hospital integrating clinical, scientific research, teaching and training functions	Provision of clinical research
Laboratory Center	A China-based drug research company primarily engaging in providing technical testing and medical technology promotion services	Provision of detection work for clinical samples

In the process of product development, we are responsible for the molecular design and selection of all the drug candidates and engage CROs to complete the animal immunization and antibody discovery for some pipeline as well as the preclinical safety and pharmacokinetics assessment for all the pipeline. We also engage CMOs/CDMOs to complete the production and supply of clinical samples and some testing work when our production capacity and testing capacity are over-loaded or some non-crucial testing project capabilities have not been built. In terms of clinical research, we are responsible for the clinical research protocols and strategies as well as the supervision of clinical implementation quality, and CROs, SMOs, hospitals and laboratory centers are responsible for the clinical operation related work. We engage the CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers on a project-by-project basis. We have taken several initiatives to make sure that these institutions perform their duties to a standard in compliance with applicable laws and regulations, as well as in line with our quality control procedures, protocols and industry benchmark to safeguard the

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integrity of the data collected from the trials and studies. We will inspect their qualifications in advance to ensure that they have the corresponding capabilities for the trials or studies. For those institutions engaging in clinical trials, we provide them with the final clinical trial protocols and a series of trainings to ensure their familiarity with the trials. They conduct the clinical trials based on our protocols, and we designate internal personnel to supervise the implementation phase. We also engage an external independent third-party company to regularly monitor our clinical trials, which is required to timely identify and supervise rectification of any non-compliance in the implementation.

The service fees we paid to our CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers during the Track Record Period were primarily based on market prevailing standards and determined through arm’s length negotiations with reference to the service scope, clinical trial type as well as the number of subjects enrolled at such site, among others.

Below is a summary of the key terms of an agreement we typically enter into with our CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers:

- *Services.* Our cooperating partner provides the high-quality research and development and technical services to us, including but not limited to the implementation and management of a preclinical or clinical research project, pre-clinical safety evaluation and PK/PD research, as specified in the agreement.
- *Term.* Our cooperating partner is required to perform its services and complete the preclinical or clinical research project within the prescribed time limit set out in each agreement, or until the cooperation agreement is terminated by both parties after negotiation.
- *Payments.* We are required to make payments to our cooperating partner in accordance with the payment schedule agreed by the parties.
- *Intellectual property rights.* We own all intellectual property rights arising from the preclinical or clinical research project.
- *Confidentiality.* Our cooperating partner is obligated to keep confidential all the data, information or contents we distributed to our cooperating partner related to the project specified in the agreement, and such obligation may survive the termination of the cooperation agreement.
- *Risk allocation.* The risk allocation between the parties and indemnification are subject to further negotiation between the parties.

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Chemistry, Manufacturing, and Controls (CMC)

CMC Team

Our CMC team provides strong support throughout the drug development process. The team is mainly responsible for upstream and downstream process development, formulation development, analytical development, process characterization and validation, pilot manufacturing, quality study, product analysis, quality control (QC) and quality assurance (QA).

Our manufacturing center was led by Dr. Yang Bin, the vice president of the manufacturing center. Dr. Yang has over ten years of experience in CMC processes management and drug development. He obtained a bachelor’s degree in pharmacy from Wuhan University, a master’ degree in microbiology and biochemical pharmacy from Shenyang Pharmaceutical University, and a doctorate in biology (biomedicine) from Jinan University. For more details about Dr. Yang’s background and credentials, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Senior Management” in this document. As of the Latest Practicable Date, our manufacturing center consisted of 28 members.

We also have a registration management team mainly responsible for the management of R&D projects, registration filings, applications for governmental research projects, as well as management of intellectual properties. Our registration management team is led by Mr. Li Si. Mr. Li has over 15 years of experience in R&D project management and registration filings. He obtained a bachelor’s degree in veterinary medicine from Huazhong Agricultural University. As of the Latest Practicable Date, our registration management team consisted of seven members.

CMC Activities and Capabilities

CMC refers to activities to properly define methods for manufacturing processes, product characteristics and testing, product storage and release to clinical usage in order to ensure that a pharmaceutical product is safe, effective and consistent between batches. Because of the complexity of therapeutic antibody, CMC is essential for antibody drug development from cell line development to cell culture process development to purification and formulation.

Although the discovery and protein engineering techniques of BsAbs are now relatively advanced, the development of BsAbs still faces many challenges in CMC comparing to the development of typical mAb drugs, including low expression titer of the target BsAbs, more impurities to remove, less stability of the intermediates, and hurdles in process scale-up.

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Therefore, in addition to the specific efforts made with molecular design, the execution of an appropriate CMC development strategy is vital to the success of the overall drug development program. Our CMC strategies include evaluating the stability of the candidate BsAb molecules at the early development stage, choosing the monoclonal cells with high titer and high purity for BsAb production, tailoring purification methods fit for the molecule characteristics, and using sustainable scale-up strategies for large-scale production.

We have extensive experience in the CMC process for the development of different BsAbs in various structures and have established strong CMC capabilities.

Process development

The process development for BsAbs can be generally divided into the upstream and downstream process development. The upstream process development, including, among others, cell line development and clone selection, media optimization, development of process strategies, and optimization of bioreactor systems, focus on generating products with a high product titer, high productivity and high quality. Meanwhile, the downstream process development focus on the production yield, process capacities and productivity, and product purity as well, using different chromatographic and non-chromatographic technologies to improve the efficiency of purification.

Built on our advanced platform technologies, our process development capability ensures the delivery of stable and high-quality BsAbs for our pre-clinical studies and clinical trials:

- *Cell line development.* Leveraging the world’s leading CHO GS-KO expression system, our CMC team is able to design and produce various types of BsAbs with different structures to obtain stable cell lines at high expression level for pre-clinical studies and clinical trials.
- *Upstream process development.* Our CMC team ensures stable and high quality products in the scale-up production. To improve the titers of target BsAbs, we optimize the manufacturing process by adopting the Fed-Batch mode to maintain a semi-continuous and semi-open cultivation system in the reactors where the nutrients are supplied aseptically. After the optimization, the average expression level for Check-BODY antibodies is nearly 6.0g/L and the average expression level for Nano-YBODY™ antibodies can reach approximately 8.0g/L, far beyond the industry average in China.
- *Downstream development.* Our CMC team improves the purity of BsAbs and assures safety. The total yield of BsAbs in our purification process can reach 75%, and the purity of the drug substance can reach 99% with low levels of impurities.

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Formulations development

Our drug formulation development team supports the development of drug product formulations and processes. Our capabilities include the development of liquid and lyophilized dosage forms. We have successfully manufactured three types of BsAb formulations for intravenous injection, intraperitoneal injection, and intravitreal injection, respectively. Through the formulation screening and optimization, the concentration of our BsAb formulations can reach 140mg/ml, with low product viscosity and great stability, exceeding the industry average in China.

Analytical development

We have developed more than 30 platform analytical methods to support our drug development. The analytical methods based on the requirements under the Chinese and U.S. Pharmacopoeias include, among others, physicochemical analysis, analysis of protein content, purity and impurity, and safety assessment. The analytical methods developed based on the liquid chromatography–mass spectrometry technology include, among others, the analysis of molecular weight, glycosylation, disulfide bonds, and peptide mapping. These analytical methods are used to analyze molecular properties and characterize molecular structures at the early stages of drug development, expediting sample testing and improving our development efficiency. At the CMC stage, we optimize the analytical methods to accommodate projects involving different BsAbs. Combined with our other developed specific analytical methods, such as charge variants analysis, isoelectric point, binding activity and biological activity, we are able to efficiently support and accelerate our product development from drug discovery to process development and manufacturing process.

GMP-compliant manufacturing

With the efforts of our quality center, we have established a GMP-compliant quality system and strictly implemented the requirements under the GMP, Chinese and U.S. Pharmacopoeias and other relevant regulations and guidelines in our product manufacturing process. As a result, we obtained the approvals by both the NMPA and FDA to conduct the clinical trials for our drug candidates M701, M802, Y150 and Y101D.

Manufacturing Facility and Collaboration with CMOs/CDMOs

As of the Latest Practicable Date, we maintained a manufacturing base of approximately 1,400 square meters with a scale of 500L (two 200L bioreactors and two 50L bioreactors) and a maximum annual production of 20-24 batches with single bioreactor to accommodate the manufacturing demands for our pre-clinical studies and earlier phases of clinical trials prior to the pivotal clinical trials for a majority of our drug candidates, including M701, Y150, Y332, and our preclinical candidates. In 2021 and 2022, the utilization rate of our manufacturing base in terms of number of days in use was approximately 69.9% and 84.4%, respectively. Unlike commercial production lines that schedule production based on continuous orders, our

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production plans are mainly determined by the periodic requirements of our clinical and pre-clinical pipelines. Due to the intermittent nature of production demand for pre-clinical studies and clinical trials, our manufacturing capacity may not be fully utilized throughout each point of the year.

Besides manufacturing conducted at our own facilities, we currently also engage third-party CMOs/CDMOs for (i) the production for pivotal clinical trials of M701, (ii) the manufacturing for pre-clinical studies and clinical trials of Y101D, which require larger production volumes. We are responsible for the development of manufacturing process of our drug candidates, and CMOs/CDMOs are responsible for the manufacturing. We selected our CMOs/CDMOs by carefully reviewing and considering various factors, including their manufacturing capacity, qualifications, geographic proximity, expertise, reputation, and costs. We have adopted procedures to ensure that the team qualifications, facilities and processes of CMOs/CDMOs comply with the relevant regulatory requirements and our internal quality management system.

We expect to engage third-party CMOs/CDMOs to manufacture certain of our products after they are commercialized. M701 and Y101D, the drug candidates that we expect to be firstly commercialized, will be initially manufactured by CDMOs upon marketing approval and later transferred to our own expanded manufacturing facility upon approval by competent regulatory authorities. We currently expect that the annual production capacity of M701 after commercialization would be around one million formulations.

While our current manufacturing capacity, in conjunction with our current plan of manufacturing outsourcing to CMOs/CDMOs, can meet the manufacturing needs for clinical trials and commercial launch of our drug candidates, we plan to further enhance our CMC and manufacturing capabilities through new machinery, instrument and equipment to improve the efficiency of our production and the quality of our products. This includes: (a) acquiring perfusion systems, fully automatic ultrafiltration systems, small-scale bioreactors, and other equipment to improve antibody expression per unit time and volume of our production line, thereby increasing the efficiency of formulation development sample preparation, (b) procuring automated filling equipment to improve filling efficiency, (c) procuring biomolecular mass spectrometers, high-performance liquid chromatography, capillary electrophoresis, and other analytical quality control equipment to conduct more comprehensive and in-depth characterization of product quality attributes, thereby streamlining product quality control process, and (d) upgrading the corresponding water systems, cold storages to optimize the compatibility of the water system with our current production site.

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Manufacturing Process

Our manufacturing process has three stages, namely, the cell culture stage, purification stage and drug product manufacturing stage, as set out below.

Cell culture

The cell culture stage is divided into cell recovery, cell expansion and cell cultivation, which generally takes 25 to 32 days.

- *Cell recovery.* Resuscitation of cells that are cryopreserved in liquid nitrogen.
- *Cell expansion.* We thaw the cells and transfer the seed cell culture from shaker flasks to larger vessels till bioreactors to reach the number of viable cells needed for production.
- *Cell cultivation.* We cultivate the cells to produce the target protein.

Purification

The purification stage is generally divided into four steps which takes seven to ten days.

- *Depth filtration.* The cell culture is further processed by removing cells and cell debris through depth filtration and filtration. Depth filtration primarily removes cells from the culture solution, and filtration primarily removes smaller cell debris and controls bioburden during the harvest.
- *Multi-step chromatography and viral inactivation.* Impurities are removed through multi-step chromatography. Leveraging our protein engineering expertise and platforms, our BsAb candidates are stable during the purification process, so the general chromatographic steps for our BsAb candidates are similar to conventional mAbs. Viruses are inactivated by altering the pH, temperature, and other conditions.
- *Nanofiltration and ultrafiltration.* Viruses of all sizes are filtered and removed by passing through nanometer-sized pores on a nanofiltration membrane. For products requiring relatively highly concentrated antibody solutions, ultrafiltration is used after nanofiltration to reach the final desired product concentration. Most of our product candidates require ultrafiltration.
- *Bulk.* Drug substances after ultrafiltration are filled into drug substances container for final product manufacturing.

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Drug product manufacturing

The drug product manufacturing stage is generally divided into two steps.

- *Preparation.* Drugs are produced using predetermined formulations. Some formulations may require adding buffer solutions.
- *Fill and finish.* The final product will undergo aseptic filtration, filling, stoppering, capping, inspection, labelling and packaging.

Quality Management

QC and QA are crucial to us. We are committed to ensuring the quality of our products through a comprehensive quality management system in accordance with the regulations of NMPA, FDA, ICH Q8 and other applicable regulations, including GMP and the standards of the Chinese and American Pharmacopoeia. The regulations cover all aspects of our operations, including process development, procurement, product manufacturing, and product storage and transportation.

Our quality management function was led by Dr. Yi Jizu, the senior vice president of the quality center. Dr. Yi has over 25 years of relevant experience in the biopharmaceutical industry. Before he joined our Group, Dr. Yi served as a chief scientist at Becton, Dickinson and Company, one of the largest global medical technology companies in the world, for over ten years. Dr. Yi obtained a bachelor’s degree in analytical chemistry and a master’s degree in physical chemistry from Central South University in China, and obtained a doctorate in biochemistry from Rutgers the State University in the United States. For more details about Dr. Yi’s background and credentials, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Supervisors” in this document. As of the Latest Practicable Date, our quality center consisted of 29 members.

We have established QC and QA procedures for monitoring operations to ensure that they meet relevant regulatory and internal quality requirements. We implement QC measures for the entire production process, mainly including control and inspection of raw materials, control of production process, inspection of intermediate and products, establishment of internationalized product release standards, research on product stability, management of deviations, changes and risks evaluation during product development and manufacturing.

Quality Control: Our QC team is mainly responsible for quality inspection of GMP-compliant manufacturing, analytical method validation, product quality standard establishment, product release testing, and stability assessment. Our QC team also inspects raw materials, intermediate products, raw liquids, finished products, and decides whether to release such materials for manufacturing.

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Quality Assurance: Our QA team is mainly responsible for managing experimental documents, overseeing manufacturing site and final products for clinical usage, compliance assessment, and the inspection and audit of our outsourced vendors. We implement strict procedures for the receiving and releasing of the raw materials used in the production, intermediate products, raw liquids and buffers, and finished products.

We have established a series of internal procedures and protocols including standard operating procedures for quality management of manufacturing process, product release and stability study. We also have standard operating procedures in place to ensure that the finished production meets the process requirements by relevant regulatory authorities. Such procedures ensure the high quality of our products used for clinical trials.

COMMERCIALIZATION

We plan to recruit capable marketing professionals and develop our capabilities of commercialization. As our current pipeline of drug candidates comes to the market, we will build an in-house commercialization team with medical and scientific background to maximize the reach of our product offering and expedite market acceptance of our products in China. We plan to seek collaboration and out-licensing opportunities to promote our drug candidates and brand in the overseas markets.

Our in-house commercialization team will initially focus on the marketing and sales of M701 once it is approved for commercialization. We plan to contract a 300-person contract sales organization (CSO) team in China with experience in selling oncology drugs and establish an in-house sales team of approximately 20 employees to meet the sales demands for M701 upon its commercialisation. We also plan to further scale up our sales team in line with increasing sales demand of M701 in the future. We plan to initiate negotiations for CSO engagement in the first half of 2024 and enter into a partnership agreement with CSO within that year. Prior to the commercial launch of M701, the CSO and our sales team will carry out pre-launch academic promotion, market access, key opinion leader maintenance, and other preparatory work, ensuring that M701 can swiftly enter the market and achieve sales upon its commercial launch. We will consider seeking inclusion of M701 into the National Reimbursement Drug List (NRDL) and other reimbursement programs to rapidly penetrate the market for the treatment of MA or MPE in China. M701 has been selected for the “National Major New Drug Innovation” program under the 12th Five-Year Plan, which we believe could be an advantage for its future inclusion into the NRDL. Leveraging the expertise and industry connections of our commercialization team, we plan to market M701 through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians to promote the clinical use of M701. We intend to identify a number of hospitals, clinics and physicians that specialize in the treatment of MA or MPE, and to visit the sites and physicians in person for pre-launch training and contact.

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We also plan to cooperate with established CSOs to promote other drug candidates, especially those facing fierce market competition from approved and late clinical-stage drug candidates that focus on similar indications and subpopulations. Moreover, we believe academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, our drug candidates after they become available for sale. We have actively participated in and will continue to attend and organize academic conferences and seminars to publicize the clinical data and research results in relation to our drug candidates in order to raise our brand awareness and recognition. We also consider supporting leading experts to report the results of their research at international and domestic conventions, symposia and other notable events to promote our brand at the foreground of the industry.

COLLABORATION AGREEMENTS

We actively seek to form strategic collaborations with resourceful partners to support the development and maximize the commercial value of our drug candidates. These collaborations allow us to utilize clinical, financial, and commercial resources of our partners, and provide us with opportunities to explore innovative modalities and therapies that employ new mechanisms through cooperation with other innovative drug developers.

Collaboration with CMS Vision

On July 26, 2022 (the “Effective Date”), we entered into an asset transfer agreement (the “CMS Agreement”) with Shenzhen Kangzhe Vision Pharmaceutical Development Co., Ltd. (深圳市康哲維盛醫藥發展有限責任公司) (formerly known as Kangzhe Pharmaceutical Research and Development (Shenzhen) Limited (深圳康哲醫藥發展有限公司)) (“CMS Vision”), a wholly-owned subsidiary of China Medical System Holdings Limited (0867.HK) (together with its subsidiaries, the “CMS Group”), to transfer all the rights and assets relating to Y400 to CMS Vision. CMS Group is a platform company linking pharmaceutical innovation and commercialization with strong product lifecycle management capability, which has been deeply engaged in several therapeutic fields, including cardio-cerebrovascular, gastrointestinal, central nervous system, dermatology and medical aesthetics, ophthalmology and pediatrics etc.

Governance

The parties shall establish a joint steering committee (“JSC”) with an equal number of representatives from each party. All decisions of the JSC shall be made by unanimous vote with each party’s representatives collectively having one vote. In case of any disagreement that cannot be resolved by negotiations, CMS Vision shall have the final decision-making authority over all matters relating to the development, manufacturing and commercialization of Y400 in the Territory (as defined below).

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Detailed Arrangement of Asset Transfer

Pursuant to the CMS Agreement, we agree to, subject to certain special arrangement with respect to United States, Europe and Japan (the “Special Arrangement”), transfer all the rights and assets relating to Y400 for any indication worldwide (the “Territory”) to CMS Vision, including but not limited to: (i) all the rights, proprietary technologies, regulatory approvals and assets (tangible and intangible) that are necessary to use, develop, register, make, have made, sell, distribute, promote and commercialize Y400; (ii) all the intellectual property rights (including trademarks, patents, know-how and applications thereof) relating to Y400 (the “Transferred IP Rights”); and (iii) all the cell bank, data, materials, information, filings and records relating to Y400, as well as all the rights obtained or otherwise generated from all the pre-clinical and clinical studies and experiments conducted for the purpose of applying and receiving regulatory approvals and intellectual property rights for Y400, that are currently owned or controlled by, or will be owned or controlled by, us and our affiliates. We also agree to grant a non-exclusive sublicense to CMS Vision with respect to an upstream cell line which we have sublicensed from a third party relating to Y400.

We have agreed to a Special Arrangement with CMS Vision with respect to the rights to Y400 in Europe, the United States, and Japan. Within 24 months upon the receipt of IND approval of Y400 in China (the “Two-year Period”), we and CMS Vision have the joint right to dispose Y400 in these jurisdictions. If we and CMS Vision agree to license, sublicense, transfer or otherwise dispose our rights to Y400 in the United States, Europe or Japan to a third party (the “Disposal Arrangement”), we and CMS Vision will equally share the gains generated from such arrangement. In this case, CMS Vision is no longer responsible to pay the corresponding milestone payments and royalties in the applicable jurisdiction. However, if a Disposal Arrangement has not been agreed and reached in any of the United States, Europe and Japan market within the Two-year Period, then the Special Arrangement will be terminated, and CMS Vision will enjoy the rights to Y400 in the corresponding jurisdiction (s) (i.e., the United States, Europe and/or Japan, as the case may be) as if such rights to Y400 were transferred to CMS Agreement since the execution date of the CMS Agreement, on the condition that they pay the corresponding milestone payments and royalties under the CMS Agreement.

Intellectual Property Arrangements

We shall transfer all the intellectual property rights specifically related to Y400, if any, that arise from the activities related to Y400 under the CMS Agreement to CMS Vision within a reasonable period requested by CMS Vision. Such intellectual property rights, if transferred, shall be treated as the Transferred IP Rights.

CMS Vision, at its own cost, is responsible for the maintenance of the Transferred IP Rights, and we will provide necessary support and assistance.

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R&D

We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. These studies include, but not limited to, pharmacology, PK, toxicology, pharmacy, CMC studies and quality and process studies for active pharmaceutical ingredients and formulations. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision’s cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China.

CMS Vision, at its own cost, is responsible for filing and obtaining the INDs, and conducting clinical trials of Y400 in the Territory, and we will provide necessary support and assistance.

The IND application for Y400 has been filed with the NMPA in January 2023 and the CDE approved the IND application for Y400. Since the execution of the CMS Agreement and up to December 31, 2022, we incurred costs and expenses of approximately RMB28.3 million in connection with our obligations under the pre-clinical studies of Y400.

Manufacturing

We have two batches of pilot-production products of Y400 and placebos in our inventories. We will deliver the two batches of Y400 and placebos to be used for Phase I and Phase II clinical trials in China to CMS Vision free of charge when the relevant clinical trials start. CMS Vision is entitled to manufacture Y400 for clinical use, use in regulatory approval or in commercial sales by itself or engage us/a CMO. If CMS Vision decides to manufacture Y400 by itself or through a CMO, we will conduct a technology transfer (“Tech Transfer”) for all the technologies and know-how relating to the manufacturing of Y400. If CMS Vision decides to engage us to manufacture Y400, parties will negotiate an agreement for the relevant rights and obligations.

Regulatory Filing and Commercialization

CMS Vision, at its own cost, is responsible for (i) filing and obtaining the regulatory approvals and marketing authorizations of Y400 in the Territory, and (ii) commercialization of Y400 in the Territory. CMS Vision will use commercially reasonable efforts to commercialize Y400 in the Territory. We will provide necessary support and assistance.

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Payments

We are entitled to receive upfront, milestone and royalty payments under the CMS Agreement. CMS Vision shall pay us an upfront payment of US\$5 million, which we have received in full. Furthermore, CMS Vision is obligated to pay us:

- (i) development milestone payment:
 - (a) in an aggregate amount of US\$9 million in the PRC, upon the receipt of the first IND approval in the PRC (expected in May 2023), the completion and delivery of a clinical study report for a Phase III clinical trial for the first indication and the receipt of the marketing approval for the first proposed indication; and
 - (b) assuming the Special Arrangement is terminated, in an aggregate amount of US\$16 million in the United States, upon the receipt of the first IND approval in the United States, the completion and delivery of a clinical study report for a Phase III clinical trial for the first indication and the receipt of the marketing approval for the first proposed indication;
- (ii) sales milestone payment: subject to the Special Arrangement, up to US\$190 million upon the achievement of certain net sales thresholds ranging from US\$300 million to US\$2 billion of Y400 in the Territory in a given calendar year; and
- (iii) royalties at single-digit percentage of the annual net sales of Y400 in the Territory.

Non-compete Covenant

We covenant that we will not conduct any Competing Activity directly or indirectly in the Territory, or provide any funding, technical, or commercial assistance, service or advice for any Competing Activity. For the purpose of CMS Agreement, Competing Activity refers to any research, development, manufacturing and/or commercialization of any drug that targets both VEGF and ANG2 in any indication (excluding Y400), or targets either VEGF or ANG2 in ophthalmology.

Termination and Dispute Resolution

The CMS Agreement will continue to be in full force and effect unless terminated due to customary termination events, including but not limited to material breach of the CMS Agreement. Any dispute relating to the CMS Agreement that is not resolved by good faith negotiation may be resolved by the Shenzhen Court of International Arbitration. As of the Latest Practicable Date, we had no disputes with CMS Vision or CMS Group.

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Collaboration with WIV

We entered into an agreement and a supplemental agreement thereof with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV), for our collaboration in the research and development of an RBD protein subunit COVID-19 vaccine, i.e., Y2019, against the SARS-CoV-2 virus in July 2020 and January 2023, respectively. Founded in 1956, WIV has been dedicated to conducting scientific research on the prevention and control of emerging infectious diseases in China and providing technology support to ensure the national biosafety.

Pursuant to our agreement with WIV, we are responsible for leading the clinical trials of Y2019, and the filing of IND and NDA submissions under the names of both parties. We completed the Phase Ia clinical trial of Y2019 on our own and at our cost.

Upon mutual agreement by the parties, WIV will conduct the antibody activity assay and animal studies during the clinical development of Y2019 and we will provide reimbursements for such activities. In the pre-clinical studies of Y2019, we, by ourselves or through a CRO, conducted the efficacy evaluation in mice (other than the evaluation involving live SARS-CoV-2 virus), the efficacy evaluation in rhesus macaques and the safety evaluation. We also manufactured and supplied the vaccines used for the pre-clinical studies. WIV, at our cost, conducted the efficacy evaluation in mice involving live SARS-CoV-2 virus, the *in vitro* efficacy evaluation in rhesus macaques (other than the evaluation we conducted) and the immunogenicity evaluation involving live SARS-CoV-2 virus in the pre-clinical studies of Y2019. We paid RMB0.7 million and RMB0.5 million to WIV in 2021 and 2022, respectively, for its contribution to the pre-clinical studies of Y2019 during the same year.

Pursuant to our agreement with WIV, we shall be the sole applicant and sole owner of a patent application filed on August 14, 2020 that is specifically related to Y2019. We and WIV shall jointly own other intellectual property rights of Y2019 arising from this collaboration. If parties intend to utilize the research results arising from this collaboration to make any publication, file any patent application, apply for any governmental subsidies, or apply for any research project, the parties shall jointly do so and jointly own the rights arising therefrom. We and WIV shall jointly share the rights and interests related to the research results and achievements of Y2019 arising from our collaboration. If the IND approval, NDA approval and/or jointly-owned intellectual property rights were transferred or licensed to third parties, we and WIV are entitled to 80% and 20% of the revenue derived thereof, respectively. Upon the commercialization of Y2019, WIV is entitled to 4% of annual sales revenue.

Our agreement with WIV shall be effective until terminated upon mutual agreement. If any disputes arise during the performance of the collaboration agreement between us and WIV, they shall be resolved through negotiations and mediation. If the disputes cannot be resolved through negotiations and mediation, any party is entitled to file a lawsuit with the court where the plaintiff resides. As of the Latest Practicable Date, we had no disputes with WIV.

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INTELLECTUAL PROPERTY

Our intellectual property is an important component of our business. We rely on a combination of patent and other intellectual property, as well as confidentiality procedures, non-disclosure agreements, employee invention assignment agreements, and other contractual restrictions to establish and protect our commercially important technologies, inventions and know-how related to our business. While we believe our intellectual property rights and applications in the aggregate are important to our competitive position, no single intellectual property right or application is material to our business as a whole.

As of the Latest Practicable Date, we owned (i) 21 issued patents in the PRC, (ii) eight issued patents in the United States, (iii) four issued patents in other jurisdictions, and (iv) 45 patent applications, including 15 pending PRC patent applications, five pending U.S. patent applications, five pending PCT patent applications which have not entered into national phases, and 20 pending applications in other jurisdictions. We believe there is no material legal impediment for us to obtain the approvals for these pending patent applications. As of the Latest Practicable Date, we self-owned all of our material patents as well as patent applications. We owned two PCT applications in relation to M701, including one PCT application that is generally applicable to our YBODY[®] molecules, including M701 and M802, and one PCT application specifically relating to M701. One PCT application had entered into national phase in major markets, including five granted patents in China, Canada, the U.S. and Japan, and one pending patent applications in China; and the other PCT application was published. For more details, please refer to the paragraphs headed “Further Information about Our Business – Intellectual Property Rights” in Appendix VI to this document.

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We have extensive patent protection for our key platform technologies and drug candidates. The following table sets forth the portfolio of patents and patent applications for our platform technologies and our clinical-stage drug candidates that are material to our business operations as of the Latest Practicable Date (for each drug candidate and technology platform, all the counterparts in its related patent family are set forth in the following table):

Technology Platform/Drug Candidate	Title of Invention	Scope of Patent Protection	Inventors ⁽⁴⁾	Jurisdiction ⁽³⁾	Patent Application Number	Status	Patent Expiration
YBODY® Platform; M802; M701; Y150	Bispecific Antibody <						

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Technology Platform/Drug Candidate	Title of Invention	Scope of Patent Protection	Inventors ⁽⁴⁾	Jurisdiction ⁽³⁾	Patent Application Number	Status	Patent Expiration
M701	Bispecific antibody and application thereof	Sequence of M701 and uses thereof	Fang Lijuan, Zhang Jing, Hua Shan, Zhou Pengfei	PCT	PCT/CN2021/131804	Accepted ⁽²⁾	N/A
Y101D	Tetravalent symmetric bispecific antibody	Sequence of Y101D and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	China	202111191003.4	Pending	N/A
Y150	Modified Fc fragment, antibody comprising same, and application thereof	Invention of antibody targeting CD38 x CD3, which includes Fc fragment with Fc function elimination effect and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	China South Korea Canada	202010977832.4 10-2021-7030413 3131033	Granted Pending Pending	N/A N/A N/A
Y2019	Novel coronavirus RBD fusion protein	Structure and sequence of RBD fusion protein and RBD dimer, preparation method, and uses thereof	Fang Lijuan, Zhang Jing, Shi Jian, Wang Xin, Luo Fang, Zhou Chi*, Lei Chuanfei*, Zhou Pengfei, Xiao Gengfu, Pan Xiaoyan, Gong Rui, Zhang Zhe	PCT	PCT/CN2020/109295	Accepted ⁽²⁾	N/A

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Technology Platform/Drug Candidate	Title of Invention	Scope of Patent Protection	Inventors ⁽⁴⁾	Jurisdiction ⁽³⁾	Patent Application Number	Status	Patent Expiration
M802	Construction and application of a bispecific antibody HER2 x CD3	Structure and sequence of M802, preparation method, and uses thereof	Zhou Pengfei, Wang Tao*, Fang Lijuan, Yang Jinxia*, Ma Yingying*, Li Na*	China	201510029954.X	Granted	2035.01.21
			Zhou Pengfei,	United States	14/803,278	Granted	2034.07.21
			Zhang Jing, Hu Lingli*, Wang Rui*, Zhou Xiang*, Fan Kesuo*	United States	15/449,656	Granted	2034.07.21

Notes:

- (1) Nationalized represents the status of a PCT patent application that it has entered into corresponding countries for subsequent national examination and the patent in specific jurisdiction come from the nationalization of the PCT patent.
 - (2) Accepted represents the status of a patent application that the application has been accepted by the applicable patent examination authorities for subsequent examination.
 - (3) In respect of two patents granted under the same jurisdiction, they correspond to the parent patent and the divisional patent, which come from the same PCT patent application, have the same original disclosure while differ in the scope of protection.
 - (4) Except for Xiao Gengfu, Pan Xiaoyan, Gong Rui and Zhang Zhe, all inventors of our material patents and patent applications are our current or previous R&D team members and all the patents are granted to us under relevant agreements. Xiao Gengfu, Pan Xiaoyan, Gong Rui and Zhang Zhe are investigators dedicating to research on the prevention and control of emerging infectious diseases and they provided us with support during the clinical development of Y2019. Throughout the collaboration, our in-house R&D team took the leading role in the clinical trials, filing of IND and NDA submission. Each of them confirmed that we are the sole applicant and sole owner of, and they will not challenge our right to exercise, any intellectual property rights arising from such patent.
 - (5) This table only lists the main jurisdictions into which the PCT applications have been entered, including China, United States, Europe, Japan, South Korea and Canada.
- * our previous employees

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Our drug candidates are developed based on the technologies of our key technology platforms. The structure and certain technical aspects of such drug candidates are derived from the technology platforms. Therefore, certain patents or patent applications with claims covering structure and sequence of antibody molecule and uses thereof are applicable to both certain drug candidates and technology platform. The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file patent applications, including China and the U.S., the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the U.S., a patent’s term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office (“USPTO”), in excess of a patent applicant’s own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly-owned patent having an earlier expiration date.

In addition, with respect to any issued patents in the U.S., China as well as certain other foreign jurisdictions, we may be entitled to obtain an extension of the patent’s term provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the U.S. FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting a BLA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, a patent may be extended only once, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Furthermore, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. Furthermore, in China, the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the owner of the patent for an innovative new drug that has been granted the marketing authorization in China to submit applications for a patent term extension of up to a maximum length of five years, in order to compensate the time required for the regulatory approval for the commercialization of such innovative new drug; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same.

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We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Intellectual Property Rights” in this document.

We also own a number of registered trademarks and pending trademark applications. We have registered trademarks for our corporate logo in China and are seeking trademark protection for our corporate logo in the jurisdictions where available and appropriate.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. For more details, please refer to the paragraphs headed “– Collaboration Agreements” in this section.

Our IP Legal Advisor conducted the freedom-to-operate searches and analyses on our Core Product and major pipeline products and litigation searches, and is of the view that there is no legal, arbitral or administrative proceedings in respect of infringement of third parties’ IP rights involving the Group during the Track Record Period and up to the Latest Practicable Date. Taking into account the views of the IP Legal Advisor, our Directors confirmed that, during the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any claims of infringement, misappropriation or other violations of third-party

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intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the research and development for any of our drug candidates in which we may be a claimant or a respondent.

The Sole Sponsor has performed the following due diligence work in relation to the intellectual property rights of the Group and no particular findings has caused or casted doubt on the Directors’ confirmation above: (i) discussed with the management of the Company on the “freedom-to-operate” analysis and any infringement of third parties’ IP rights by the Group; (ii) conducted due diligence interview with the IP Legal Advisor, and reviewed the intellectual property due diligence report on the Company issued by the IP Legal Advisor which contains freedom-to-operate analysis and litigation search in relation to intellectual property rights. Nothing has come to the attention of the Sole Sponsor that would cause it to cast doubt on the IP Legal Advisor’s view above; (iii) reviewed the PRC legal opinion issued by the PRC legal advisor to the Company which contains intellectual property, litigation and compliance information of the Group, and no instance of litigation, arbitration or administrative penalty of infringement of third parties’ IP rights by any member of the Group has been identified during the Track Record Period and up to the Latest Practicable Date in the PRC legal opinion; (iv) engaged background search agent to conduct background search and litigation search on the Group, and no findings suggested that the Group was involved in any litigation, non-compliance or negative news in relation to infringement of third parties intellectual property rights; and (v) together with Merits & Tree Law Offices, the PRC legal advisor to the Sole Sponsor, conducted desktop search on the Company and no instance of infringement of third parties intellectual property rights by the Company has been identified.

DATA PRIVACY AND PROTECTION

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations.

We have established procedures to protect the confidentiality of patients’ data. We maintain policies requiring our personnel to be trained to collect and safeguard personal information and require our CROs to have data protection clauses in our agreements with them. They are responsible for safeguarding data in their possession. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel.

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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 (the “ICF”). We will obtain consent from patients if any use of data falls outside the scope of ICF.

We have a number of ongoing or planned clinical studies in China and may in the future, conduct clinical trials the United States. 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 and the United States. Together with our CROs and other collaboration partners, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern the 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). Our Directors confirm that we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with applicable PRC laws and regulations for data privacy and protection as of the Latest Practicable Date.

COMPETITION

The markets for biopharmaceutical industry and BsAbs are evolving and highly competitive. While we believe that our research and development capabilities enable us to establish a favorable position in the industry, we encounter competition from international and domestic biopharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, academic institutions and research institutions. For more information on the competitive landscape of our drug candidates, please refer to the section headed “Industry Overview” in this document and the paragraphs headed “– Our Drug Candidates” in this section.

We believe the primary competitive factors in our markets are identification of potential targets, mechanisms and pathways for drug development, molecule screening and design, efficacy and safety of drug candidates, manufacturing efficiency and commercialization development. We expect the competition will become more intensive in the future as additional players enter into the segments. Any drug candidates that we successfully develop and commercialize will compete with existing drugs or any new drugs that may become available in the future. For potential impact of market competition, please refer to the paragraphs headed “Risk Factors – Risks Relating to the Research and Development of our Drug Candidates – We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do” in this document.

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RAW MATERIALS AND SUPPLIERS

During the Track Record Period, our purchases mainly included third-party contracting services for preclinical evaluation and clinical trials of our drug candidates, raw materials, consumables, machines, and equipment.

Our inventory consists of raw materials and consumables used for our drug candidates’ development. We regularly monitor our inventories and endeavor to keep an optimal inventory level in line with the expected usages in the near term. We have established an inventory management system which records inventory data. Our Directors confirmed that our inventory control system and policies had been effective and we did not experience any material shortage in supply or overstock of inventories during the Track Record Period and up to the Latest Practicable Date.

Our major suppliers primarily consist of CROs, CDMOs, CMOs, and suppliers of equipment, devices, and consumable items located in China.

We select our suppliers by considering their product/service quality, costs, delivery standards, industry reputation and compliance with relevant regulations and industry standards.

For the years ended December 31, 2022 and 2021, the aggregate purchases attributable to our five largest suppliers in each year were RMB68.0 million and RMB24.5 million, respectively, representing 48.4% and 37.7% of our total purchases for the same years, respectively. Purchases attributable to our single largest supplier in each year were RMB50.0 million and RMB9.0 million, accounting for 35.3% and 13.8% of our total purchases for the same years, respectively. We believe that we maintain strong and stable relationships with our major suppliers.

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The following table sets forth details of our five largest suppliers for the year ended December 31, 2022:

Ranking	Supplier	Supplier Background	Products/ Services Purchased	Length of Business Relationship	Credit Term Granted	Purchase Amount	% of Total Purchase
						(RMB in thousands)	
1	Supplier A	A China-based non-clinical CRO primarily engaging in drug safety assessment	Preclinical drug metabolism and toxicological evaluation, and clinical testing services	8 years	Up to 30 days	49,666	35.3%
2	Supplier C	A China-based medical company primarily engaging in technology promotion and application services	Clinical outsourcing services	2.5 years	20 days	5,873	4.2%
3	Supplier I	A U.K.-based company primarily engaging in providing testing and production services	Cell bank assay and virus inactivation removal process validation services	3.5 years	30 days	4,640	3.3%
4	Supplier K	A China-based clinical trial site	Clinical research services	less than 1 year	14 days	4,021	2.9%
5	Supplier B	A China-based biomedical company primarily engaging in providing one-stop services for biomacromolecule drugs	Manufacture services	2.5 years	5 days	3,848	2.7%
Total						68,048	48.4%

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The following table sets forth details of our five largest suppliers for the year ended December 31, 2021:

Ranking	Supplier	Supplier Background	Products/ Services Purchased	Length of Business Relationship	Credit Term Granted	Purchase Amount <i>(RMB in thousands)</i>	% of Total Purchase
1	Supplier F	A China-based biotechnology company primarily engaging in large animal experiments, new drug research and evaluation	Preclinical drug metabolism and toxicological evaluation services	4 years	10 days	8,961	13.8%
2	Supplier G	A Switzerland-based chemical and biotechnology company primarily engaging in providing product development services	Raw materials (host cells)	3.5 years	30 days	4,344	6.7%
3	Supplier H	A China-based biomedical company primarily engaging in providing one-stop services for biopharmaceutical industry	Manufacture services	1 year	30 days	4,228	6.5%
4	Supplier D	A China-based pharmaceutical company primarily engaging in R&D of new drug and technology	Clinical outsourcing services	5 years	22 days	4,045	6.2%
5	Supplier I	A U.K.-based company primarily engaging in providing testing and production services	Cell bank assay and virus inactivation removal process validation services	3.5 years	30 days	2,930	4.5%
Total						24,508	37.7%

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Supplier F, with purchase amount of RMB9.0 million in 2021, was our largest supplier for the same year, primarily due to the fact that supplier F is located in Wuhan and is able to supply adequate materials necessary for our research and development at lower price when certain imported materials necessary for our research and development became scarce due to the impact of the COVID-19 pandemic. Since late 2021, with the COVID-19 related restrictive measures gradually lifted domestically and globally, we resumed and renewed collaborations with suppliers based on our R&D progress. We entered into an agreement with supplier A in late 2021 for their services in 2022. Accordingly, the purchase amount attributable to supplier A was RMB50.0 million in 2022 and supplier A was the largest supplier for the same year.

Relationship with Supplier D

Supplier D is indirectly wholly-owned by CSPC through its subsidiary as of the Latest Practicable Date, and is regarded as our related party and a connected person. Supplier D was selected as our CRO for its relatively stable relationship with major research centers and the collaboration was determined after arm’s length negotiations. Under our collaboration agreement, we owned all intellectual property and trial results and supplier D must maintain strict confidentiality with respect to the information it acquired from us during clinical trials. For the years ended December 31, 2021 and 2022, the aggregate purchases attributable to supplier D were RMB4.0 million and RMB2.2 million, respectively. The CRO collaboration with supplier D has ended in 2022 and the Company has no intention to continue such collaboration after the [REDACTED]. In order to proceed with relevant clinical research using the original database, the Company entered into service agreements with supplier D in September 2022 and October 2022, respectively, based on arm’s length negotiations. Pursuant to such service agreements, the Company shall pay supplier D service fees on a quarterly basis for using the databases and other ancillary services provided by supplier D. The agreements will respectively expire in June 2023 and November 2023 and the Company has no intention to renew such agreements upon their expiration. For the year ending December 31, 2023, the aggregate service fees under such agreements are expected to be approximately RMB0.3 million. Except for the aforesaid transactions with supplier D, we did not have other historical and, as of the Latest Practicable Date, do not have intention to enter into any transactions with CSPC and/or its associates.

During the Track Record Period, except for supplier D, none of our five largest suppliers was our related parties. Except for supplier D, none of our Directors or their associates or, to the knowledge of our Directors, any Shareholder with over 5% of the share capital of our Company has any interest in any of our five largest suppliers during the Track Record Period.

In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. Other than the agreements with certain CROs and CMOs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. We generally have credit periods of nil to 90 days.

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EMPLOYEES

As a biotechnology company, our employees are our valuable resource. As of the Latest Practicable Date, we had a total of 122 full-time employees, all of whom were in China. The following table sets forth a breakdown of our employees categorized by function as of the Latest Practicable Date:

Function	Number	Percentage
R&D	99	81.1%
General and Administrative	23	18.9%

We also plan to develop our internal sales and marketing team preparing for the commercialization of our drug candidates in the future.

Employment Agreements with Key Management and R&D Staff

We enter into standard labor, confidentiality and non-compete agreements with our employees. The non-compete restricted period typically expires two years after the termination of employment, and we agree to compensate the employees with a certain percentage of their pre-departure salary during the restricted period. Our standard employment contract, which we used to employ each of our employees, 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 such employee’s work.

We recruit and retain highly engaged and motivated team players who are driven by our commitment, and are excited to contribute to the development of next-generation immunotherapies leveraging their extensive experience. Our success depends largely on the efforts and expertise of all employees who are an integral part of our business. As we are dedicated to expanding our talent pool to support our future development, our business will not be materially and adversely affected by the departure of any single key management or R&D staff. We believe that we are in a good position to create an equitable, inclusive and diverse workplace while maintaining a good working relationship with our employees. As of the Latest Practicable Date, we had not experienced any major labor disputes.

Training and Development

We offer employees a variety of professional development opportunities and encourage a performance-driven environment. We focus on creating a robust culture to encourage retention and engagement. Given our emphasis on our integrated in-house research and development capabilities, we attach great importance to internal talent growth. We continually pursue progression opportunities for our staff through various internal and external training and development programs, including pre-job training, on-the-job practice, cross-training, special skills training, and talent echelon development training.

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Employee Benefits

We are committed to making sure that working conditions throughout our business network are safe and that employees are treated with care and respect. We believe we offer our employees competitive compensation packages, reflecting our stakeholder-centric ethos which we believe leads to sustainable and durable growth. As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurances, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing funds. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses and certain allowances of our employees, up to a maximum amount specified by the local government regulations from time to time. Our compensation package also comprises year-end bonuses, communication, transport and meal allowances, staff dormitory, paid leaves, and holiday benefits. In addition, we provide career development opportunities and promote an inventive, collaborative, and productive work environment, which we believe fosters robust and long-lasting self-motivation for our employees.

During the Track Record Period, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees, which we believe will not bring any material adverse effect to our operations or financial position. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. We have obtained certain confirmation letters issued by the relevant competent social insurance and housing provident fund authorities confirming that there is no record of any member of our Group that hires employees being imposed administrative penalties by the relevant authorities for violation of the relevant laws and regulations. As advised by our PRC Legal Advisor, the likelihood that we are subject to centralized collection of historical arrears and any material penalties due to our failure to make full contributions of social insurance premium and housing provident funds for some of our employees during the Track Record Period is remote, based on the interviews with competent authorities.

LAND AND PROPERTIES

Land, Construction-in-Progress and Owned Properties

As of the Latest Practicable Date, we had land use right to one land parcel located in Wuhan, Hubei, with a site area of approximately 25,533.4 square meters. We also had ownership on ten properties with an aggregate gross floor area of 3,772.5 square meters as of the Latest Practicable Date.

We acquired such land parcel in 2012 for the construction of our manufacturing facility pursuant to a land grant contract (the “Land Grant Contract”) with Wuhan Municipal Bureau of Natural Resources and Planning, East Lake High-tech Development Zone Branch (the “Wuhan Bureau of Natural Resources and Planning”). Under the Land Grant Contract, the construction work on this parcel should be completed within two years from the date of the Land Grant Contract. However, we experienced certain delays in completing the construction

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project on such land parcel, primarily due to the delay in delivery of such land parcel by the Wuhan Bureau of Natural Resources and Planning and our change of manufacturing plan to outsource the manufacturing of M701 to qualified CMOs at this stage, as well as the impact of COVID-19 outbreaks.

Under PRC laws, if a company fails to complete its construction works within the required time frame in the relevant land use right grant contract, the competent PRC authorities may impose liquidated damages on such company from the required construction completion date under the land use right grant contract, and the land parcel may be subject to forfeiture to the PRC government if the construction has not meet relevant capital investment requirement. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – The PRC government may impose fines or other penalties on us if we fail to comply with the terms of the land grant contracts” in this document.

We conducted a consultation with the Wuhan Bureau of Natural Resources and Planning on September 21, 2022, with respect to our suspended constructions on such land parcel. During the consultation, the Wuhan Bureau of Natural Resources and Planning confirmed that (i) the land parcel under the Land Grant Contract is not recognized as an idle land, and (ii) after the completion of the [REDACTED], if we could complete the construction work on such land parcel in accordance with the construction standards stipulated in the Land Grant Contract, the Wuhan Bureau of Natural Resources and Planning will not impose any penalty to us. As confirmed by our PRC Legal Advisor, the Wuhan Bureau of Natural Resources and Planning is the competent authority to conduct such a consultation. Based on the foregoing, our PRC Legal Advisor is of the view that, after the completion of the [REDACTED], if we could complete the construction work on such land parcel in accordance with the construction standards stipulated in the Land Grant Contract, the risks of our being subject to penalty and forfeiture of land parcel with respect to such land parcel is remote.

The following table summarizes the properties we owned as of the Latest Practicable Date:

Location	Use of Property	Gross Floor Area (m ²)
East Lake High-tech Development Zone Wuhan, Hubei Province	Employee Dormitory	81.16
	Employee Dormitory	81.16
	Employee Dormitory	81.16
	Employee Dormitory	81.04
	Leased Out	81.04
	(to an independent third party)	
	Employee Dormitory	136.36
	Office	811.78
	R&D	811.78
	R&D	811.78
	R&D	795.25

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Leases

As of the Latest Practicable Date, we leased four properties with a total of approximately 1,295.08 square meters from independent third parties as our office premises and research and development center in the PRC; and one of our subsidiaries leased one property with a total of approximately 3,230.59 square meters from our Company as such subsidiary’s office premise and research and development center. We believe our current facilities are sufficient to meet our near-term needs, and additional 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.

The following table sets forth the details of our leased properties from independent third parties:

<u>Location</u>	<u>Type of Property</u>	<u>Address</u>	<u>Gross Floor Area (m²)</u>	<u>Lease Term</u>	<u>Expiry Date</u>
Wuhan, Hubei	Office premise and R&D center	Rooms 301-307, 3/F, Block D, Building C1, Biolake Park, No. 666 High-tech Avenue, East Lake High-tech Development Zone Wuhan, Hubei Province	510	13 months	June 9, 2024
Wuhan, Hubei	Office premise	Overhead 1/F, Building C2-3, Biolake Park, No. 666 High-tech Avenue, East Lake High-tech Development Zone Wuhan, Hubei Province	120	One year	December 31, 2023

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Location	Type of Property	Address	Gross Floor		Expiry Date
			Area (m ²)	Lease Term	
Nanjing, Jiangsu	Office premise and R&D center	Rooms 903-909, 926-928, Block A, Phase I of Zhongdan Ecology and Life Science Industrial Park, No. 3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu Province	565	Three years	December 19, 2025
Nanjing, Jiangsu	Office premise	Room 635, Block A, Phase I of Zhongdan Ecology and Life Science Industrial Park, No. 3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu Province	100	One year	March 5, 2024

The lessor who leased us the property with gross floor area of approximately 120 square meters in Wuhan, Hubei, has not provided us with its property ownership certificate or any other documentation proving its right to own or lease the property. As advised by our PRC Legal Advisor, the lack of such documentation may invalidate our lease agreements with such lessor. We believe that such defect will not have a material and adverse impact on our business operations considering that there are sufficient alternative locations for us to choose from and the relocation is convenient.

Pursuant to the applicable PRC laws and regulations, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, six of our leases had not been filed with the governmental authorities. For one of such six leases, our Company is the lessor and one of our subsidiaries is the lessee. The failure to file and obtain property leasing filing certificates for such six leases, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed. If such fines are imposed, the maximum penalty we may be required to pay would be approximately RMB70,000. For details of the risk associated with the unregistered lease agreements, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We are subject to risks associated with leasing space” in this document. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising

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from the non-registration of our lease agreements, and had not experienced any dispute arising out of, or in relation to, our leased properties. As advised by our PRC Legal Advisor, the non-registration of our lease agreements does not affect the validity of such agreements, and we believe such non-compliance is unlikely to have a material adverse effect on our business operations and financial performance. We will take all practicable and reasonable steps to ensure that the unregistered leases are registered.

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, this document is exempted from compliance with the requirements of section 342(1)(b) 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 require a valuation report with respect to all our interests in land or buildings, for the reason that, as of December 31, 2022, we had no single property with a carrying amount of 15% or more of our consolidated total assets.

Upon expiration of our leases, we will need to negotiate for renewal of the leases or relocate. There are sufficient alternative locations for us to choose from, but we may incur additional costs in relation to the potential relocation. During the Track Record Period, we did not experience any dispute arising out of our leased properties.

AWARDS AND RECOGNITIONS

We have received various awards and qualifications for our projects and entities. The following table sets forth the key selected awards and qualifications for which we received government grants as of the Latest Practicable Date:

Year of Grant	Award/Recognition	Issuing Authority
2023	Second Prize of Science and Technology Progress Award of Hubei Province	People’s Government of Hubei Province
2022	“Specialized and Innovative” Small Giant Enterprise of Hubei Province	Department of Economy and Information Technology of Hubei Province
2022	National Science and Technology Small and Medium Enterprise	Ministry of Science and Technology of the PRC

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Year of Grant	Award/Recognition	Issuing Authority
2021	“Gazelle Enterprise”	Science and Technology Bureau of Wuhan East Lake High-tech Development Zone
2021	Strategic Innovation and Entrepreneurship Team of Hubei Province	Department of Science and Technology of Hubei Province
2020	Hubei Provincial Intellectual Innovation Demonstration Base	Department of Science and Technology of Hubei Province
2018	Postdoctoral Research Station	Ministry of Human Resources and Social Security of the PRC
2018	Top Ten Innovative Enterprise	Biolake of Wuhan East Lake High-tech Development Zone
2017	Hubei Immunological Targeted Antibody Engineering Technology Research Center	Department of Science and Technology of Hubei Province
2016	Hubei Provincial Research Center for Bispecific Antibody Engineering Technology	Development and Reform Commission of Hubei Province
2016	Intellectual Property Pioneer	Intellectual Property Administration of Wuhan East Lake High-tech Development Zone

ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We acknowledge our environment protection and social responsibilities and are aware of the environmental, energy, climate-related and workplace safety issues that may impact our Group’s business operation. We are committed to complying with environmental, social and governance (“ESG”) reporting requirements upon [REDACTED].

Our Board has overall responsibility for (i) overseeing and determining our Group’s environmental, social, and climate-related risks and opportunities that impact our Group, (ii) establishing ESG related targets of our Group, (iii) adopting the ESG related policies, and (iv) reviewing our Group’s performance in ESG matters.

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Environment Protection

We endeavor to reduce negative impacts on the environment through our commitment to energy saving and sustainable development.

We had not yet commercialized any of our drug candidates and had not started large-scale commercial production as of the Latest Practicable Date. We currently manufacture certain of our existing drug candidates for R&D purposes only. Accordingly, we produce limited air pollution, wastewater, biological solid waste or other hazardous wastes. We have adopted internal policies for environmental risk prevention to ensure compliance with the requirements of the applicable national, industrial and local standards, laws, regulations and policies, including, but not limited to, (i) strict compliance with the GMP regulations and relevant pollutant emissions standards; and (ii) periodic environmental evaluations on exhaust gas detection and emissions, hazardous waste disposals, noise emissions, and waste water detection and emissions.

During the Track Record Period and up to the Latest Practicable Date, we had not received any fines or penalties associated with the breach of any environmental laws or regulations. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

We monitor our hazardous wastes on a periodic basis and make continuous efforts in working towards the target of reducing the hazardous wastes discharge. Our wastewater discharge levels in relation to the research and testing decreased from approximately 1.7 tons in 2021 to 0.9 tons in 2022, and the solid waste we transferred to the third parties decreased from 10.9 tonne in 2021 to 7.4 tonne in 2022, respectively. For any potential hazardous wastes we produce from R&D activities, we contract with qualified third parties for the disposal of hazardous materials and wastes. In 2021 and 2022, we incurred costs of approximately RMB217,333 and RMB39,518, respectively, in this regard. We require their operational qualifications in accordance with relevant governmental laws and regulations. The third-party waste treatment service providers issue written records for the transfer of hazardous wastes and we keep such records for our internal review and compliance. We will make continuous endeavors to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact.

Resource Consumption

To reach our goal for sustainable development, we oversee our environmental protection performance in various aspects, such as efficiency in the use of resources and energy consumption. We monitor our electricity and water consumption levels and implement measures to improve energy efficiency and water conservation. In 2021 and 2022, the electricity consumption levels were approximately 1.1 million kWh and 1.1 million kWh in

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aggregate, respectively with our water consumption levels reaching approximately 3.2 thousand tons and 4.4 thousand tons in aggregate, respectively. The table below sets forth an analysis of our environmental protection performance with industry average during the Track Record Period:

	As of/For the year ended December 31	
	2021	2022
Our Company		
Number of employees	111	120
Electricity consumption (kWh)	1,052,334	1,070,588
Per employee electricity consumption (kWh)	9,480	8,922
Water consumption (tons)	3,153	4,422
Per employee water consumption (tons)	28	37
Industry Peers*		
Electricity consumption (kWh)	5,165,192	6,172,679
Per employee electricity consumption (kWh)	18,164	10,759
Water consumption (tons)	41,258	50,294
Per employee water consumption (tons)	83	97

Source: Annual Reports or ESG Reports of Listed Biotech Companies under Chapter 18A of the Listing Rules as of the Latest Practicable Date

Following the ESG evaluation system standards in China and the market practice of industry pioneers, we aim to avoid or reduce the adverse impact on the environment caused by our operations and services, formulate environmental management plans to continuously improve our energy consumption efficiency and ensure all of our operations comply with governmental environment-related regulations and requirements. Our current target is to establish a comprehensive ESG governance mechanism and system for our Company and the historical energy consumption levels during the Track Record Period will serve as a foundation for developing more relevant energy reduction strategies and settling appropriate reduction targets for us in the future. We intend to reduce our per employee electricity and water consumption by 10% in 2026 with a view of balancing our R&D and manufacture progress in the next three years, and our environmental commitment to maximize electricity utilization and reduce water waste in our daily operation through process optimization.

To achieve our goals, we have already implemented the following environmentally friendly measures:

- encouraging all staff to reduce the production of paper waste, reduce consumption of water resources and electrical appliances by posting water-saving or power-saving signs in eye-catching areas to cultivate our employees’ awareness of environment protection;

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- encouraging our employees to avoid printing hard copies and requiring double-sided printing whenever possible;
- encouraging teleconferences as opposed to physical meetings to reduce travel;
- reducing the usage of air conditioning, including requirements on lowest temperature;
- regularly conducting inspections of our laboratory equipment in order to check for abnormal conditions, and make prompt report to avoid potential damages;
- carrying out manual check after shift to eliminate unnecessary lighting;
- promoting recycling schemes, seeking alternative ways of disposing of and reducing waste in environmental-friendly ways; and
- strictly complying with and fully implementing all relevant environmental laws and regulations.

During the Track Record Period, we complied with the relevant environmental laws and regulations in all material aspects and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations.

Climate Change

In view of the nature of our business, to the best knowledge of our Directors, the climate change will not have any major impact on our business operation. In the case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans in addition to the life insurance contributed by our Group to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make corresponding contingency and disaster preparedness plans, and we believe that we have the ability to deal with climate crisis. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of environmental, social and climate-related issues.

Potential transition risk may result from a lower-carbon economy, which entails climate-related regulations and policy change and reputational risk. Currently, the National Development and Reform Commission and the Ministry of Ecology and Environment have jointly issued the Opinions on Further Strengthening the Cleanup of Plastic Pollution, laying out a five-year roadmap to restrict the use, production and sale of plastic products by 2020, 2022, and 2025, respectively. Our Group will work with the suppliers to comply with such regulations, and we will monitor the scope to ensure our works meet the expectations of the regulators.

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Workplace Safety

We commit to promoting work-life balance and create a positive workplace for all of our employees.

We have adopted and maintained a series of rules, standard operating procedures, and measures, including those required under the GMP standards, to maintain our employees’ health and we emphasize providing a safe working environment for our employees as well as our clinical trial participants. We implement safety guidelines to set out information about potential safety hazards, safe practices, accident prevention and accident reporting as core aspects, 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 conduct safety inspections of our laboratories and manufacturing facilities on a regular basis and new employees are required to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we conduct training sessions on fire control safety and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents. Furthermore, we have taken measures in relation to the occupational health and monitoring management, as an effort to protect the health and rights of our employees, prevent occupational diseases, and provide proper placement and compensation for employees diagnosed with occupational diseases.

We are also dedicated to providing fair and equal treatment and career opportunities to all of our employees. We prohibit any form of discrimination based on gender, family origin, disability, religious beliefs, or race throughout our recruiting process. To the best knowledge of our Directors and during the Track Record Period, we did not encounter any significant workplace safety incidents.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover adverse events in our clinical trials. We maintain insurance for our employees in accordance with relevant PRC laws and regulations. We believe that our insurance coverage is adequate to cover our key assets, facilities, and liabilities.

PERMITS, LICENSES AND OTHER APPROVALS

Our PRC Legal Advisor has advised that as of the Latest Practicable Date, we have obtained all material licenses, permits, approvals and certificates from the relevant government authorities that are material for the business operations of our Group.

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RISK MANAGEMENT AND INTERNAL CONTROL

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies and procedures that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems.

Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. For more details, please refer to the section headed “Risk Factors” in this document. We are also exposed to various market risks currency and interest rate risks, credit risks, and liquidity risks that arise in the normal course of our business. For more details, please refer to the paragraphs headed “Financial Information – Market Risk Disclosure” in this document.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an audit committee to review and supervise our financial reporting process and internal control system;
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions, and information disclosure;
- provide anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an internal control consultant (the “Internal Control Consultant”) to perform certain agreed-upon procedures (the “Internal Control Review”) in connection with the internal control of our Company in certain aspects, including entity-level controls, financial reporting and disclosure controls, sales and collection management, purchase and payment management, inventory management, fixed assets management, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review, identified internal control deficiencies and provided recommendation accordingly. We have adopted the

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corresponding remediation actions to improve the effectiveness of internal control system. The Internal Control Consultant performed a follow-up review with regard to those actions taken by us and there are no further material findings identified in the process of the follow up Review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company’s internal control.

After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.

LEGAL PROCEEDINGS AND COMPLIANCE

As of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the Company or any of our Directors which could have a material and adverse effect on the research and development of our drug candidates, our financial condition or results of operations. Potential future litigation or any other legal or administrative proceeding, regardless of the merit or outcome, is likely to result in substantial costs, diversion of our resources, and have a negative impact on our reputation and brand image, which in turn, would have negative impact on our business, financial condition, and results of operations. For potential impact of legal or administrative proceedings on us, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation” in this document.

We are of the view that, during the Track Record Period and up to the Latest Practicable Date, we had complied, in all material respects, with all relevant laws and regulations in the jurisdictions we operate in, our Directors confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our Group’s business operations. For potential impact of certain non-compliance incidents on us, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We are subject to risks associated with leasing space” and “Business – Employees – Employee Benefits” in this document.

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You should read the following discussion and analysis in conjunction with our audited consolidated financial information, included in the Accountants’ Report in Appendix I to this document, together with the respective accompanying notes. Our consolidated financial information has been prepared in accordance with IFRSs.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to the future events and financial performance that involve risks and uncertainties. These statements are based on our assumptions and analysis made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” in this document.

For the purpose of this section, unless the context otherwise requires, references to 2021 and 2022 refer to our financial year ended December 31 of such year. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

We are a biotechnology company dedicated to developing BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. We have designed and developed a pipeline of seven clinical-stage drug candidates.

We currently have no products approved for commercial sales and have not generated any revenue from product sales. We have not been profitable and have incurred operating losses during the Track Record Period. For the years ended December 31, 2021 and 2022, we had loss and total comprehensive expense of RMB148.5 million and RMB188.9 million, respectively.

We expect to incur an increased amount of operating expenses for the next several years as we further our preclinical research, continue the clinical development of, seek regulatory approval for and manufacture, our drug candidates, launch our pipeline products, and add personnel necessary to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a public company. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our drug candidates.

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BASIS OF PREPARATION

Our Company was established in Wuhan, the PRC on July 8, 2010 as a limited liability company. On January 13, 2022, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. For details, please refer to the paragraphs headed “History, Development and Corporate Structure – Establishment and Corporate Development” in this document.

The consolidated statements of profit or loss and other comprehensive income, consolidated statements of changes in equity and consolidated statements of cash flows of the Group for each of the years ended December 31, 2021 and 2022, and the consolidated statements of financial position of the Group as of December 31, 2021 and 2022, and a summary of significant accounting policies and other explanatory information (together, the “**Historical Financial Information**”) have been prepared in accordance with the International Financial Reporting Standards (“**IFRSs**”) issued by the International Accounting Standards Board (“**IASB**”).

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our ability to successfully complete the clinical development, obtain regulatory approvals and achieve commercialization of our drug candidates

All of our drug candidates are still in development. Our ability to generate revenue and realize profitability depends on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. As of the Latest Practicable Date, we have strategically designed and developed our pipeline of seven drug candidates under clinical development in China. With respect to M701, our Core Product, we are currently conducting a Phase II clinical trial in treating MA. We also commenced the Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022. For more details, please refer to the section headed “Business” in this document.

Although we currently do not have any drug that is approved for commercial sales and have not generated any revenue from sales of our drug candidates, we expect to commercialize one or more of our drug candidates over the coming years as they move towards the final stages of development. Once our drug candidates are commercialized, our business and results of operations will be driven by the market acceptance and sales of our commercialized drugs and by our manufacturing capacity to meet the commercial demand. However, the commercialization may require significant marketing efforts before we are able to generate any revenue from sales of our drug candidates. If we fail to achieve the degree of market acceptance, we may not be able to generate revenue as expected.

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Our cost structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and administrative expenses.

We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates. Research and development expenses have been and are expected to continue to be a major component in our cost structure. During the Track Record Period, our research and development expenses primarily consisted of: (i) technical service fees; (ii) raw materials costs; (iii) employee benefit expenses, including non-cash share-based payments; (iv) depreciation and amortization expenses; and (v) others. For detailed information, please refer to the paragraphs headed “– Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Research and Development Expenses” in this section. For the years ended December 31, 2021 and 2022, our research and development expenses amounted to RMB112.9 million and RMB157.3 million, respectively, of which our non-cash share-based payments were RMB25.0 million and nil for the years ended December 31, 2021 and 2022, respectively.

Our current research and development activities mainly relate to the clinical advancement of our Core Product and other drug candidates. We expect our research and development expenses to continue to increase for the foreseeable future as we advance the clinical development of our drug candidates to maximize their clinical and commercial potential, as well as to explore and advance the clinical development of our drug candidates for the treatment of additional indications.

During the Track Record Period, our administrative expenses primarily included: (i) employee benefits expenses, including non-cash share-based payments; (ii) professional parties’ fees; (iii) depreciation and amortization expenses; (iv) business development fees; (v) freight and miscellaneous fees; and (vi) others. For detailed information, please refer to the paragraphs headed “– Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Administrative Expenses” in this section. For the years ended December 31, 2021 and 2022, our administrative expenses amounted to RMB31.5 million and RMB20.5 million, respectively, of which our non-cash share-based payments were RMB14.6 million and RMB1.6 million for the years ended December 31, 2021 and 2022, respectively.

We expect our cost structure to evolve as we continue to develop and expand our business. As the preclinical studies and clinical trials of our drug candidates continue to progress and as we gradually commercialize our product pipeline, we expect to incur additional costs in relation to, among other things, preclinical study and clinical trial expenses, CMC expenses, raw materials procurements, manufacturing and sales and marketing. To support our business growth, we also expect to expand our headcount, particularly for our clinical development and

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commercialization teams, and incur higher employee costs as a result. Additionally, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong following the completion of the [REDACTED].

Funding for our operations

During the Track Record Period, we funded our operations primarily through equity financings and loans. Going forward, we expect to primarily fund our operations with cash on hand. In the event of successful commercialization of one or more of our drug candidates, we may also generate revenue from future licensing arrangements and sales of our commercialized drug products. However, with the continuing expansion of our business and product pipelines, we may require further funding through public or private offerings, debt financings, collaboration arrangements and licensing arrangements or other funding sources. Any fluctuation in the funding for our operations will impact our cash flow and our results of operations.

Redemption liabilities on ordinary shares

From December 2020 to July 2021, we entered into a series of investment agreements with independent investors, namely the Series B Financing, Series B+ Financing, and Series B++ Financing agreements, which we recognized as financial liabilities at amortized costs. As a result, as of December 31, 2020, we recorded redemption liabilities on ordinary shares of RMB105.0 million. However, our redemption liabilities on ordinary shares are non-cash items and have ceased to impact our financial performance since August 30, 2021, as we no longer recorded any redemption liabilities on ordinary shares since then, and our investors’ redemption rights were terminated on the same day. Our redemption liabilities on ordinary shares were then derecognized and credited to other reserve. With the continuing expansion of our business and development of our drug candidates, we may require further funding through private equity financings.

Our present and future collaborations

We actively seek strategic collaborations with resourceful partners to support the development and commercialization of our drug candidates. For instance, we are developing Y2019 in a collaboration arrangement, and have transferred the interests of Y400 to a third party. For more details, please refer to the paragraphs headed “Business – Collaboration Agreements” in this document. These collaborations allow us to leverage our partners’ resources, and provide us opportunities to explore innovative modalities and therapies that employ new mechanisms through cooperation with other innovative drug developers. Our ability to identify resourceful partners and enter into prospective collaboration agreements may affect the commercial value of our drug candidates.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The 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 IFRSs. The preparation of our consolidated financial statements requires our Directors to make estimates, judgment and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities and their accompanying disclosures, and the disclosure of contingent liabilities at the end of each period of the Track Record Period. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We based our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances. 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 judgment are described below. Please refer to Notes 4 and 5 to the Accountants’ Report set out in Appendix I to this document for further details of our accounting policies, estimates and judgments.

Critical Accounting Policies

The Historical Financial Information has been prepared in accordance with IFRSs issued by the IASB. For the purpose of preparation and presenting of the Historical Financial Information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the Historical Financial Information includes the applicable disclosures required by the Listing Rules and by the Companies Ordinance.

The Historical Financial Information has been prepared on the historical cost basis except for certain financial instruments which are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

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, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, we take into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value for measurement and/or disclosure purposes in the Historical Financial Information is determined on such a basis, except for share-based payment transactions that are within the scope of IFRS 2 *Share-based Payment*, leasing transactions that are accounted for in accordance with IFRS 16 *Leases*, and measurements that have some similarities to fair value but are not fair value, such as net realizable value in IAS 2 *Inventories* or value in use in IAS 36 *Impairment of Assets*.

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In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

Government grants

Government grants are not recognized until there is reasonable assurance that the grants will be received and that all attaching conditions will be complied with.

Government grants are recognized in profit or loss on a systemic basis over the periods in which we recognize as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that we should purchase, construct or otherwise acquire non-current assets are recognized as deferred income in the consolidated statement of financial position and transferred to profit or loss on a systematic and rational basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under “other income”.

Share-based payments

Equity-settled share-based payment transactions

Share options/restricted shares (“RS”) granted to employees

Equity-settled share-based payments to employees are measured at the fair value of the equity instruments at the grant date.

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The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on our estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payments reserve). At the end of each reporting period, we revise our estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve. For RS that vest immediately at the date of grant, the fair value of the RS granted is expensed immediately to profit or loss.

Modification to the terms and conditions of the share-based payment arrangements

When the terms and conditions of an equity-settled share-based payment arrangement are modified, we recognize, as a minimum, the services received measured at the grant date fair value of the equity instruments granted, unless those equity instruments do not vest because of failure to satisfy a vesting condition (other than a market condition) that was specified at grant date. In addition, if we modify the vesting conditions (other than a market condition) in a manner that is beneficial to the employees, for example, by reducing the vesting period, we take the modified vesting conditions into consideration over the remaining vesting period.

The incremental fair value granted, if any, is the difference between the fair value of the modified equity instruments and that of the original equity instruments, both estimated as at the date of modification.

If the modification occurs during the vesting period, the incremental fair value granted is included in the measurement of the amount recognized for services received over the period from modification date until the date when the modified equity instruments are vested, in addition to the amount based on the grant date fair value of the original equity instruments, which is recognized over the remainder of the original vesting period.

If the modification occurs after vesting period, the incremental fair value granted is recognized immediately, or over the vesting period if additional period of service is required before the modified equity instruments are vested.

If the modification reduces the total fair value of the share-based arrangement, or is not otherwise beneficial to the employee, we continue to account for the original equity instruments granted as if that modification had not occurred.

Property and equipment

Property and equipment are tangible assets that are held for use in supply of services, or for administrative purposes other than construction in progress. Property and equipment are stated in the consolidated statements of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

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Properties in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by our Directors, including costs of testing whether the related asset is functioning properly. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

When our Group makes payments for ownership interests of properties which includes leasehold land and building elements, the entire consideration is allocated between the leasehold land and the building elements in proportion to the relative fair values at initial recognition. To the extent the allocation of the relevant payments can be made reliably, interest in leasehold land is presented as “right-of-use assets” in the consolidated statement of financial position. When the consideration cannot be allocated reliably between non-lease building element and undivided interest in the underlying leasehold land, the entire properties are classified as property and equipment.

Depreciation is recognized so as to write off the cost of assets other than properties under construction less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

Intangible assets

Research and development expenditure

Expenditure on research activities is recognized as expenses in the period in which it is incurred.

An internally-generated intangible asset arising from development activities is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible assets so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible assets;

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- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

An intangible asset is derecognized on disposal, or when no future economic benefits are expected from use or disposal. Gains and losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognized in profit or loss when the asset is derecognized.

Financial liabilities and equity

Classification as debt or equity

Debt and equity instruments issued by a group entity are classified as either financial liabilities or as equity in accordance with substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by us are recognized at the proceeds received, net of direct [REDACTED] costs.

Financial liabilities

All financial liabilities are subsequently measured at amortized cost using the effective interest method.

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Financial liabilities at amortized cost

Financial liabilities included trade and other payables, bank borrowings, amount due a subsidiary, amount due to a related party and redemption liabilities on ordinary shares are subsequently measured at amortized cost, using the effective interest method.

Redemption liabilities of ordinary shares

For the redeemable obligation on certain ordinary shares issued by our Company as detailed in Note 29 of the Accountants’ Report in Appendix I to this document, financial liabilities are recognized by our Company to purchase our own equity instruments for cash and measured at the present value of the redemption amount. The debit recognized in equity on initial recognition is presented as “other reserves”. The financial liabilities are subsequently measured at amortized cost, of which interest is accrued in accordance with the effective interest method in profit or loss. When the redemption rights related to the ordinary shares are terminated, redemption liabilities on ordinary shares are extinguished and credited to equity.

Derecognition of financial liabilities

We derecognize financial liabilities when, and only when, our obligations are discharged, canceled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

Critical Accounting Judgments and Estimates

The following are the critical judgments that our Directors have made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in the Historical Financial Information.

Research and development expenses

Research and development expenses incurred on our drug product pipelines are capitalized and deferred only when we can demonstrate (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale; (ii) our intention to complete and our ability to use or sell the asset; (iii) how the asset will generate future economic benefits; (iv) the availability of resources to complete the pipeline; and (v) the ability to measure reliably the expenditure during the development. Research and development expenses which do not meet these criteria are expensed when incurred. Our Directors assess the progress of each of the research and development projects and determine whether the criteria are met for capitalization. During the Track Record Period, all research and development expenses were expensed when incurred.

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DESCRIPTION OF SELECTED COMPONENTS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the years indicated derived from our consolidated statements of profit or loss and other comprehensive income set forth in the Accountants’ Report in Appendix I to this document:

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Other income	12,798	2,560
Other gains and losses	716	671
Research and development expenses	(112,893)	(157,329)
Administrative expenses	(31,497)	(20,525)
[REDACTED] expenses	[REDACTED]	[REDACTED]
Finance costs	(14,972)	(2,468)
Loss before tax	(148,518)	(188,866)
Loss and total comprehensive expenses for the year	(148,518)	(188,866)

Other income

During the Track Record Period, our other income mainly consisted of: (i) government grants; (ii) income from sales of protein antigen; (iii) bank interest income; and (iv) others.

Government grants included grants received from various PRC government authorities mainly in connection with the enterprise development support and subsidies which had certain conditions imposed by the respective PRC government authorities. The relevant conditions have been fully met upon recognition. Income from sales of protein antigen, which is not considered as the principal business of the Group, was related to sales to a single customer, an Independent Third Party. Bank interest income included interest from bank deposits. Others included other miscellaneous non-operating income.

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The following table sets forth a breakdown of our other income for the years indicated:

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Government grants	12,093	2,254
Income from sales of protein antigen	472	–
Bank interest income	162	283
Others	71	23
	<u>12,798</u>	<u>2,560</u>

Other gains and losses

During the Track Record Period, our other gains and losses mainly consisted of: (i) loss on disposal of property and equipment; (ii) gains from changes in fair value of financial assets at FVTPL; and (iii) others.

The following table sets forth a breakdown of our other gains and losses for years indicated:

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Loss on disposal of property and equipment	(545)	(3)
Gain from changes in fair value of financial assets at FVTPL	1,261	671
Others	–	3
Total	<u>716</u>	<u>671</u>

Loss on disposal of property and equipment represented our losses from disposing certain assets. Gain from changes in fair value of financial assets at FVTPL represented the gain from recognizing fair value changes in wealth management products and structured deposits purchased by us and managed by financial institutions in China. For further details, please refer to the paragraphs headed “– Financial Assets at FVTPL” in this section.

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Research and development expenses

During the Track Record Period, our research and development expenses mainly consisted of: (i) technical service fees; (ii) raw materials costs; (iii) employee benefit expenses; (iv) depreciation and amortization expenses; and (v) others. Technical service fees mainly related to our engagement with third party service providers including CROs, SMOs, CMOs/CDMOs, clinical trial sites and principal investigators, as well as other expenses incurred in connection with our pre-clinical studies and clinical trials. Raw materials costs mainly included expenses for procuring materials and consumables used to support our preclinical studies and clinical trials. Employee benefit expenses consisted of wages and salaries, share-based payment, bonuses and other employee benefits for research and development employees. Particularly, the total share-based payment expenses for our R&D employees were RMB25.0 million and nil in 2021 and 2022, respectively. Depreciation and amortization expenses mainly represented the depreciation and amortization of our right-of-use assets, property and equipment for research and development purposes. Others mainly included general expenses including utilities, traveling and transportation expenses and other miscellaneous expense incurred for research and development purposes.

The following table sets forth breakdowns by activities of our research and development expenses in absolute amount and as percentages of our total research and development expenses for the years indicated:

	Year Ended December 31,			
	2021		2022	
	Amount	%	Amount	%
	<i>(RMB in thousands, except for percentages)</i>			
Technical service fees	42,163	37.3	101,247	64.4
Raw materials costs	17,595	15.6	21,481	13.7
Employee benefit expenses	41,997	37.2	24,072	15.3
Depreciation and amortization expenses	6,390	5.7	5,722	3.6
Others	4,748	4.2	4,807	3.0
Total	112,893	100.0	157,329	100.0

The technical service fees increased significantly from RMB42.2 million in 2021 to RMB101.2 million in 2022, primarily due to (i) increased service fees incurred for the PK, PD and safety evaluation studies of Y400 and Y332 conducted in 2022, in preparation of their IND applications in January 2023; (ii) increased expenses incurred for the Phase II clinical trial for M701 in treating MA that commenced in December 2021 and the Phase Ib/II clinical trial for M701 in treating MPE that commenced in November 2022; and (iii) increased expenses incurred for the Phase Ia clinical trial of Y2019 that commenced in April 2022.

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The non-cash R&D expenses we incurred during the Track Record Period consisted primarily of (a) share-based payment expenses for R&D employees of RMB25.0 million and depreciation and amortization expenses of RMB6.4 million in 2021; and (b) depreciation and amortization expenses of RMB5.7 million in 2022.

The share-based payment expenses for R&D employees decreased from RMB25.0 million in 2021 to nil in 2022, as the Group did not grant share-based payments for R&D employees in 2022. The depreciation and amortization expenses remained relatively stable from 2021 to 2022.

The following table sets forth the research and development expenses incurred for our drug candidates in absolute amount and as percentages of our total research and development expenses for the years indicated:

	Year Ended December 31,			
	2021		2022	
	Amount	%	Amount	%
	<i>(RMB in thousands, except for percentages)</i>			
M701	9,867	8.7	23,529	15.0
MA	9,779	8.7	18,036	11.5
MPE⁽¹⁾	88	0.0	5,493	3.5
Solid Tumor⁽¹⁾				
Y101D	27,085	24.0	13,627	8.7
Y150	4,791	4.2	5,248	3.4
Y2019	23,740	21.0	21,290	13.5
M802	10,995	9.7	3,344	2.1
Y332	5,484	4.9	32,771	20.8
Y400	8,372	7.4	41,044	26.1
Other drug candidates⁽²⁾	22,559	20.0	16,477	10.4
Total	<u>112,893</u>	<u>100.0</u>	<u>157,329</u>	<u>100.0</u>

Notes:

- (1) In 2021 and 2022, the R&D expenses incurred for the pre-clinical studies of M701’s treatment of MPE and solid tumor were generally applied to both indications.
- (2) Other drug candidates include our other in-house-developed, early stage drug candidates.

FINANCIAL INFORMATION

We have invested significant R&D resources for the R&D of M701 since we commenced the molecular design of M701 in July 2013. Based on our management accounts, between 2013 and 2020, the approximate aggregate amount of the R&D expenses incurred for M701 were higher than the approximate aggregate amount of the R&D expenses incurred for any other drug candidate then being developed by us, both in absolute amount and as percentages of our Group’s total R&D expenses incurred for the same period.

The R&D expenses for M701 incurred during the Track Record Period consisted primarily of (i) expenses incurred for the clinical trials for the Phase I and Phase II clinical trials of M701 for the treatment of MA; and (ii) expenses incurred for the pre-clinical studies of M701 for the treatment of MPE and solid tumor. The R&D expenses for M701 increased from RMB9.9 million in 2021 to RMB23.5 million in 2022, mainly due to (i) the increased technical service expenses incurred for the Phase II clinical trial of M701 for the treatment of MA, as we commenced such Phase II clinical in December 2021; and (ii) the increased expenses for the safety evaluation of M701 for the treatment of MPE and solid tumor.

The R&D expenses for Y101D decreased from RMB27.1 million in 2021 to RMB13.6 million in 2022, mainly because (i) we incurred substantial R&D expenses for pre-clinical studies of Y101D in 2021 in preparation of its IND application; and (ii) we did not incur significant expenditures for a period in 2022 during which we were preparing for the clinical trials of Y101D.

The R&D expenses for Y150 remained relatively stable at RMB5.2 million in 2022, as compared to RMB4.8 million in 2021. The R&D expenses for Y2019 remained stable from RMB23.7 million in 2021 to RMB21.3 million in 2022.

The R&D expenses for M701 in 2021 accounted for approximately 8.7% of the total R&D expenses in 2021, lower than such percentages of Y101D (24.0%) and Y2019 (21.0%) in 2021. This was primarily owing to (i) the significant R&D expenses incurred for the pre-clinical studies of Y101D before it initiated the Phase I clinical trial in patients with metastatic or locally advanced solid tumors in China in August 2021; (ii) the higher R&D expenses incurred for the pre-clinical studies and the subsequent production of Y2019 for future clinical trials in 2021. As to M701, the Phase I clinical trial of M701 for the treatment of MA was completed in January 2022; thus, a large portion of R&D activities for M701 in 2021 were mainly related to clinical data analysis and preparation of clinical trial report without significant expenditures, leading to a lower percentage in 2021.

Along with the advancement of the development of M701, the R&D expenses for M701 was RMB23.5 million in 2022, accounting for approximately 15.0% of the total R&D expenses in 2022, higher than such percentages of Y101D, Y150 and Y2019 in the same year. Meanwhile, the R&D expenses for M701 in 2022 were lower than the R&D expenses for Y332 (20.8%) and Y400 (26.1%) in 2022 by proportion, primarily due to the significant expenses incurred for the accelerated pre-clinical studies of Y332 and Y400 in 2022 in preparation of their IND applications in January 2023.

FINANCIAL INFORMATION

Administrative expenses

During the Track Record Period, our administrative expenses mainly consisted of: (i) employee benefits expenses; (ii) professional parties’ fees; (iii) depreciation and amortization expenses; (iv) business development fees; (v) freight and miscellaneous fees; and (vi) others. Employee benefits expenses consisted of wages and salaries, share-based payments, bonuses and other employee benefits for administrative employees. Professional parties’ fees represented our engagement of professional parties during our ordinary course of business. Depreciation and amortization expenses represented the depreciation and amortization of our right-of-use assets, property and equipment for administrative purposes. Business development expenses represented administrative fees incurred as a result of our business development activities. Freight and miscellaneous fees comprised of transportation expenses. Others mainly included lease expenses, utility fees, traveling expenses, office consumables, and other miscellaneous expenses. The following table sets forth breakdowns of our administrative expenses in absolute amount and as percentages of our total administrative expenses for the years indicated:

	Year Ended December 31,			
	2021		2022	
	Amount	%	Amount	%
	<i>(RMB in thousands, except for percentages)</i>			
Employee benefits expenses	21,396	67.9	9,114	44.4
Professional parties’ fees	3,176	10.1	2,914	14.2
Depreciation and amortization expenses	1,227	3.9	1,222	6.0
Business development fees	1,499	4.8	2,704	13.2
Freight and miscellaneous fees	563	1.8	457	2.2
Others	3,636	11.5	4,114	20.0
Total	31,497	100.0	20,525	100.0

[REDACTED] expenses

[REDACTED] expenses represent expenses incurred for our proposed [REDACTED] and [REDACTED]. For the years ended December 31, 2021 and 2022, we recorded [REDACTED] expenses of RMB[REDACTED] and RMB[REDACTED], respectively.

FINANCIAL INFORMATION

Finance costs

During the Track Record Period, our finance costs consisted of: (i) interest expenses on bank and other borrowings; (ii) interest expenses on lease liabilities; and (iii) interest expenses on redemption liabilities on ordinary shares. For further details, please refer to the paragraphs headed “– Redemption liabilities on ordinary shares” in this section. The following table sets forth breakdowns of our finance costs in absolute amount and as percentages of our total finance costs for the years indicated:

	Year Ended December 31,			
	2021		2022	
	<i>Amount</i>	<i>%</i>	<i>Amount</i>	<i>%</i>
	<i>(RMB in thousands, except for percentages)</i>			
Interest expenses on bank and other borrowings	1,208	8.1	2,448	99.2
Interest expenses on lease liabilities	42	0.3	20	0.8
Interest expenses on redemption liabilities on ordinary shares	13,722	91.6	–	–
Total	14,972	100.0	2,468	100.0

PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Year ended December 31, 2022 Compared to Year ended December 31, 2021

Other income

Our other income decreased from RMB12.8 million in 2021 to RMB2.6 million in 2022. The decrease was primarily due to: (i) the decrease of government grants of RMB9.8 million in 2022 as government grants are non-recurring in nature, subject to the satisfaction of certain conditions each year, and (ii) the decrease of income from sales of protein antigen of RMB0.5 million in 2022 as it was an one-off transaction in 2021 based on a technical service agreement with an Independent Third Party.

Other gains and losses

Our other gains remained stable at RMB0.7 million in 2021 and 2022.

FINANCIAL INFORMATION

Research and development expenses

Our research and development expenses increased from RMB112.9 million in 2021 to RMB157.3 million in 2022. The increase was primarily due to: (i) the expenses incurred from the technical service for Phase I clinical trials of Y150, Y101D and Y2019, and the Phase II clinical trial of M701; and (ii) the increase in our purchases of raw materials as a result of increased production of stock solutions and reagents for Y332 and Y400. Such increase was partially offset by the decrease in employee benefits expenses as we did not grant share-based payments for research and development employees in 2022.

Administrative expenses

Our administrative expenses decreased from RMB31.5 million in 2021 to RMB20.5 million in 2022, primarily due to the decrease in share-based payments for administrative employees in 2022 and was partially offset by the increase of business development fees.

[REDACTED] expenses

Our [REDACTED] expenses increased from RMB[REDACTED] in 2021 to RMB[REDACTED] in 2022, mainly in relation to the engagement of professional parties in preparation for our proposed [REDACTED].

Finance costs

Our finance costs decreased from RMB15.0 million in 2021 to RMB2.5 million in 2022, primarily due to the decrease in interest expenses on redemption liabilities on ordinary shares by RMB13.7 million in 2022, which mainly resulted from the termination of redemption rights in connection with our Series B Financing, Series B+ Financing and Series B++ Financing on August 30, 2021 and was partially offset by the increase in interest expenses on bank and other borrowings by RMB1.2 million in 2022 as a result of an increase in the principal amount of borrowings.

Loss and total comprehensive expenses

As a result of the foregoing, our loss and total comprehensive expenses increased from RMB148.5 million in 2021, to RMB188.9 million in 2022.

FINANCIAL INFORMATION

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE 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 have been derived from the Accountants’ Report set out in Appendix I to this document:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Total non-current assets	74,517	63,885
Total current assets	125,638	238,957
Total assets	<u>200,155</u>	<u>302,842</u>
Total current liabilities	56,908	146,960
Net current assets	68,730	91,997
Total non-current liabilities	83	–
Total liabilities	56,991	146,960
Net assets	<u>143,164</u>	<u>155,882</u>
Capital and reserves		
Paid-in capital	165,072	–
Share capital	–	182,000
Reserves	<u>(21,908)</u>	<u>(26,118)</u>
Total equity	<u>143,164</u>	<u>155,882</u>

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The following tables sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of
	2021	2022	April 30,
			2023
	(RMB in thousands)		(Unaudited)
Current assets			
Inventories	8,914	10,623	7,856
Prepayments, deposits and other receivables	14,139	27,814	36,698
Financial assets at FVTPL	19,500	47,000	15,000
Cash and cash equivalents	83,085	153,520	104,737
	<u>125,638</u>	<u>238,957</u>	<u>164,291</u>
Current liabilities			
Trade and other payables	22,677	33,555	33,526
Bank borrowings	28,000	76,500	49,000
Amount due to a related party	4,659	–	–
Lease liabilities	397	169	769
Deferred income	1,175	2,975	2,975
Advance from transfer agreement	–	33,761	33,761
	<u>56,908</u>	<u>146,960</u>	<u>120,031</u>
Net current assets	<u><u>68,730</u></u>	<u><u>91,997</u></u>	<u><u>44,260</u></u>

Our net current assets decreased from RMB92.0 million as of December 31, 2022 to RMB44.3 million as of April 30, 2023. The decrease was primarily due to a decrease in our current assets, partially offset by a decrease in our current liabilities. Our current assets decreased from RMB239.0 million as of December 31, 2022 to RMB164.3 million as of April 30, 2023, primarily due to (i) a decrease in cash and cash equivalents of RMB48.8 million to repay certain bank loans as scheduled and for our working capital; and (ii) a decrease in financial assets at FVTPL of RMB32.0 million, as a result of the redemption of wealth management products to meet the cash needs for our R&D activities. The decrease in our current assets was partially offset by the increase in prepayments, deposits and other receivables of RMB8.9 million. Our current liabilities decrease from RMB147.0 million as of December 31, 2022 to RMB120.0 million as of April 30, 2023, primarily due to a decrease in bank borrowings of RMB27.5 million as we repaid certain amount of bank loans as scheduled.

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Our net current assets increased from RMB68.7 million as of December 31, 2021 to RMB92.0 million as of December 31, 2022, primarily due to an increase in our current assets, which was partially offset by an increase in our current liabilities. Our current assets increased from RMB125.6 million as of December 31, 2021 to RMB239.0 million as of December 31, 2022, primarily due to (i) an increase in cash and cash equivalents of RMB70.4 million, as a result of the completion of the Series C Financing in October 2022; (ii) an increase in financial assets at FVTPL of RMB27.5 million, in relation to our investment in certain structured deposits and wealth management; and (iii) an increase in prepayments, deposits and other receivables of RMB13.7 million, mainly attributable to the increase of prepayments for research and development services. Our current liabilities increased from RMB56.9 million as of December 31, 2021 to RMB147.0 million as of December 31, 2022, primarily due to (i) an increase in bank borrowings of RMB48.5 million; (ii) an increase in advance from transfer agreement of RMB33.8 million, as a result of the fixed upfront fee of US\$5 million pursuant to the CMS Agreement that we entered into to transfer all rights and assets relating to Y400 to CMS Vision, which will be required to refund upon certain conditions; and (iii) an increase in trade and other payables of RMB10.9 million, mainly attributable to an increase in accrued research and development expenses. The increase in our current liabilities was partially offset by the decrease in amount due to a related party of RMB4.7 million. The amount due to a related party was trade in nature in relation to technical service fees we incurred for the CRO services provided to us by such related party and had been fully settled as of the Latest Practicable Date. For further details, please refer to Note 25 to the Accountants’ Report in Appendix I to this document.

Inventories

During the Track Record Period, our inventories consisted of materials purchased for our research and development projects. Our inventories increased from RMB8.9 million as of December 31, 2021 to RMB10.6 million as of December 31, 2022, mainly due to our continuous research and development of our drug candidates and increasing demands for inventories for such activities. As of April 30, 2023, approximately RMB7.5 million, or 70.4% of our inventories as of December 31, 2022, had been subsequently consumed or sold.

The following table sets forth an aging analysis of our inventories as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Within six months	5,522	3,326
Over six months and within one year	2,040	5,432
One to two years	1,314	1,616
Two to three years	38	245
Over three years	—	4
	<u>8,914</u>	<u>10,623</u>

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Considering that (i) over 80% of the inventories as of December 31, 2022 were aged less than one year, (ii) as of April 30, 2023, over 70% of our inventories as of December 31, 2022 had been subsequently consumed or sold, (iii) our inventories are for regular consumption in our R&D activities rather than for commercial sale, and (iv) we had not experienced any material shortage in supply or overstock of inventory during the Track Record Period and up to the Latest Practicable Date, our Directors are of the view that there is no material recoverability issue for our inventories and no provision. As a result, we did not make any provision for our inventories at the end of each reporting period. We have implemented effective inventory control system and policies and regularly monitor our inventory to reduce the risk of overstocking.

Prepayments, deposit and other receivables

Our prepayments, deposit and other receivables included: (i) prepayments for research and development services which were mainly related to upfront fees paid for research and development services for the clinical and non-clinical studies of our drug candidates; (ii) prepayments for [REDACTED] expenses and [REDACTED] costs; (iii) deferred [REDACTED] costs; (iv) advance to staff; and (v) others. The table below sets forth a breakdown of our prepayments, deposit and other receivables as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Prepayments for research and development services	12,511	19,703
Prepayments for [REDACTED] expense and [REDACTED] costs	[REDACTED]	[REDACTED]
Deferred [REDACTED] costs	[REDACTED]	[REDACTED]
Advance to staff	328	337
Others	279	657
Subtotal	14,139	27,814

Our prepayments, deposit and other receivables increased from RMB14.1 million as of December 31, 2021 to RMB27.8 million as of December 31, 2022, primarily due to (i) the increase of prepayments for research and development services of RMB7.2 million, which mainly included upfront fees paid for the clinical and non-clinical studies of our drug candidates; and (ii) the increased deferred [REDACTED] costs of RMB5.7 million, which will be deducted from equity upon [REDACTED], as a result of the increased expenses incurred for our preparation for the [REDACTED].

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The following table sets forth an aging analysis of our prepayments, deposit and other receivables as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
0-30 days	5,207	6,622
31-90 days	2,838	5,681
91-180 days	4,993	5,238
181-365 days	931	4,498
Over 365 days	170	5,775
	<u>14,139</u>	<u>27,814</u>

As of April 30, 2023, approximately RMB4.4 million, or 15.8% of our prepayments, deposit and other receivables as of December 31, 2022, had been subsequently utilized or settled.

Financial assets at FVTPL

During the Track Record Period, our financial assets at FVTPL included structured deposits and wealth management products, both of which were managed by financial institutions in China. The table below sets forth a breakdown of our financial assets at FVTPL as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Structured deposits	17,000	32,000
Wealth management products	2,500	15,000
Subtotal	<u>19,500</u>	<u>47,000</u>

We recorded financial assets at FVTPL of RMB19.5 million as of December 31, 2021, mainly in relation to our investment in certain structured deposits and wealth management products. Our financial assets at FVTPL increased from RMB19.5 million as of December 31, 2021 to RMB47.0 million as of December 31, 2022, mainly due to the increase of our investment in those structured deposits and wealth management products in 2022.

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As part of our treasury management, we invested in certain structured deposits and wealth management products to better utilize excess cash when our cash sufficiently covered our ordinary course of business. We have implemented a series of internal control policies and rules setting forth overall principles as well as detailed approval process of our treasury management activities, to ensure that the purpose of investment is to preserve capital and liquidity until free cash is used in our primary business and operation. Specifically, our treasury management policies include, but not limited to: (i) we only allow investments in structured deposits and other principal-guaranteed wealth management products, if any; (ii) the structured deposits and wealth management products we invest in should be issued by large commercial banks in the PRC; (iii) our finance department is in charge of assessment and purchase of structured deposits and wealth management products after considering the amount of our available funds and future capital needs while ensuring liquidity safety under the principle of maximizing the return on funds; (iv) before purchasing any structured deposits or wealth management products, the head of our finance department will assess the risk associated with the underlying products based on the risk classification provided by the issuing financial institutions; and (v) an application form should be submitted to and approved by the head of our finance department before any purchase of structured deposits and wealth management products. The approval from our Board of Directors is required for any significant investment in structured deposits and wealth management products. Our head of finance department, Mr. Yuan Rong, has 20 years of working experience in corporate finance management including treasury management. Under our treasury management policies, we adopted a prudent approach in selecting treasury management products and government-guaranteed structured deposits from reputable financial institutions in China.

Moreover, in addition to treasury management policies, we have in place a set of policies and procedures to manage our financial risks, such as capital management policies, R&D expenditure management policies, budget management policies and financial management policies. Our finance department is responsible for the implementation of such policies and procedures, and regularly monitors our financial system to ensure its accurate and stable operation and minimize our risk exposure.

Our structured deposits were denominated in RMB and managed by a financial institution in China. The principal is guaranteed by the relevant financial institutions with expected yield of 1.48% and 1.30% per annum as at December 31, 2021 and 2022, respectively, and the actual yield to be received is uncertain until settlement. Our structured deposits had a maturity date within a year and were classified as financial assets measured at FVTPL. Our purchased wealth management product was denominated in RMB and managed by a financial institution in China with expected rate of return ranging from 2.55% to 3.10% and 2.80% to 4.10% per annum as of December 31, 2021 and 2022, respectively. Our wealth management products had a maturity date within a year and were classified as financial assets measured at FVTPL. To control our risk exposure, we have in the past sought, and may continue in the future to seek, principal-guaranteed structured deposits and other products that provide better investment returns than term deposits at commercial banks.

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After the [REDACTED], we intend to continue to invest in financial assets at FVTPL strictly in accordance with our internal policies and the requirements under Chapter 14 of the Listing Rules.

Cash and cash equivalents

During the Track Record Period, our cash and cash equivalents included cash at bank and short-term bank deposits with maturity less than three months. The following table sets forth a breakdown of our cash and cash equivalents as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Cash at bank	34,830	153,520
Short-term bank deposits with maturity less than three months	48,255	—
	<u>83,085</u>	<u>153,520</u>

Our cash and cash equivalents increased from RMB83.1 million as of December 31, 2021 to RMB153.5 million as of December 31, 2022, primarily due to an increase of cash at bank of RMB118.7 million as a result of the completion of the Series C Financing in October 2022, which was partially offset by a decrease of short-term bank deposits with maturity of less than three months of RMB48.3 million as a result of our redemption of short-term bank deposits with maturity less than three months.

Trade and other payables

During the Track Record Period, our trade and other payables primarily consisted of (i) trade payables for research and development expenses; (ii) accrued research and development expenses; (iii) other payables to government; (iv) accrued staff costs and benefits; (v) accrued [REDACTED] expenses; and (vi) accrued [REDACTED] costs.

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The following table sets forth the breakdown of our trade and other payables as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Trade payables for research and development expenses	5,380	3,214
Accrued research and development expenses	7,761	15,503
Other payables to government ⁽¹⁾	3,600	3,600
Accrued staff costs and benefits	2,885	3,456
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]
Accrued [REDACTED] costs	[REDACTED]	[REDACTED]
Government grants received on behalf of staff	275	877
Other tax payables	362	454
Payables for acquisition of property and equipment	117	47
Others	193	77
	<u>22,677</u>	<u>33,555</u>

Note:

- (1) Other payables to government relate to a government subsidy we received for construction of R&D facilities, with a condition that the construction should be completed and approved by the relevant PRC government authority before December 31, 2016. As of December 31, 2021 and 2022, we had not fulfilled such condition. This subsidy is repayable to the relevant PRC government authority on demand. As of the Latest Practicable Date, we had not received any notice from any government authority to repay the government subsidy.

Our trade and other payables increased from RMB22.7 million as of December 31, 2021 to RMB33.6 million as of December 31, 2022, mainly due to an increase in accrued research and development expenses of RMB7.7 million, primarily as a result of our continuous research and development efforts.

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The following table sets forth an aging analysis of our trade payables for research and development expenses based on the invoice dates as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
0-30 days	2,524	1,795
31-90 days	1,746	628
91-180 days	482	61
181-365 days	169	207
Over 365 days	459	523
	<u>5,380</u>	<u>3,214</u>

As of April 30, 2023, approximately RMB20.3 million, or 60.5% of our trade and other payables as of December 31, 2022, had been subsequently settled.

Advance from transfer agreement

We recorded advance from transfer agreement of RMB33.8 million as of December 31, 2022, mainly in relation to the fixed upfront payment of US\$5 million by CMS Vision pursuant to the CMS Agreement.

On July 26, 2022, we entered into the CMS Agreement with CMS Vision to transfer all the rights and assets relating to Y400 to CMS Vision. We believe we can benefit from the collaboration with CMS Vision. We strategically focus on the development of BsAb-based therapies, while CMS Vision has expertise in the ophthalmology field and focuses on identification, development and commercialization of urgent needed ophthalmic diagnosis and treatment. Moreover, as a wholly-owned subsidiary of a Hong Kong listed company, China Medical System Holdings Limited (0867.HK), CMS Vision has greater financial, technical and human resources, more established commercialization infrastructure as well as more experience in late-stage clinical development of drug candidates than we do. As a result, we believe that our collaboration with CMS Vision can augment the R&D process and accelerate the commercialization of Y400. For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with CMS Vision” in this document.

Redemption liabilities on ordinary shares

During the Track Record Period, we recognized the Series B, Series B+ and Series B++ preferred shares with redemption rights issued to investors as financial liabilities at amortized cost. We used the effective interest method to determine the amortized cost of ordinary shares with redemption liabilities which takes into account of the repurchase price on the earliest redemption date of each series and maturity dates. For details, please refer to Note 29 to the Accountants’ Report set out in Appendix I to this document.

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We no longer recorded any redemption liabilities on ordinary shares since August 30, 2021 and we recorded nil and nil redemption liabilities on ordinary shares as of December 31, 2021 and 2022, as a result of termination of our obligation to repurchase the Series B, Series B+ and Series B++ preferred shares from investors.

Property and equipment

Our property and equipment recorded under non-current assets consisted of buildings, equipment, furniture and fixture, motor vehicles, leasehold improvement, and construction in progress.

Our property and equipment decreased from RMB51.0 million as of December 31, 2021 to RMB46.0 million as of December 31, 2022. The decrease was primarily due to the decrease of the carrying amount of equipment as a result of depreciation of RMB6.3 million.

Right-of-use assets

Our right-of-use assets recorded under non-current assets primarily arose from our leasehold lands and leased properties. The table below sets forth our right-of-use assets as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Leasehold lands	8,498	8,287
Leased properties	484	220
	<u>8,982</u>	<u>8,507</u>

Our right-of-use assets decreased from RMB9.0 million as of December 31, 2021 to RMB8.5 million as of December 31, 2022, mainly due to routine amortization per year.

Value added tax recoverable

Value added tax recoverable recorded under non-current assets represents our value-added tax (VAT) input tax credit that cannot be refunded by the competent authority within one year and would be utilized to deduct our VAT output tax in the future. Such VAT input tax credit is resulted from the difference between our VAT input tax (arising from our purchase of property, equipment, as well as raw materials and other consumables) and our VAT output tax (arising from sales of equipment and materials). Such amounts can be refunded by the competent authority and be utilized to deduct our VAT output tax in the future.

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Our value added tax recoverable significantly decreased from RMB13.8 million as of December 31, 2021 to RMB8.7 million as of December 31, 2022. The decrease of RMB5.2 million was primarily due to our application for a tax refund of our value added tax recoverable.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of liquidity consist of cash and cash equivalents, which we have historically generated primarily through capital contributions from our shareholders, private equity financing 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. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. We expect our liquidity requirements will be satisfied by a combination of [REDACTED] from the [REDACTED], cash generated from our operations after the commercialization of our drug candidates and funds received from potential out-licensing arrangements. With the continuing expansion of our business, we may require further funding through public or private offerings, debt financings, collaboration arrangements or other sources.

Cash Flows

The following table sets forth a summary of our cash flows for the years indicated:

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Operating cash flow before movements in working capital	(87,161)	(178,821)
Movements in working capital	(11,549)	2,118
Income tax paid	—	—
Net cash used in operating activities	(98,710)	(176,703)
Net cash (used in) from investing activities	(19,933)	5,804
Net cash from financing activities	81,034	241,334
Net (decrease) increase in cash and cash equivalents	(37,609)	70,435
Cash and cash equivalents at beginning of the year	120,694	83,085
Cash and cash equivalents at the end of the year	83,085	153,520

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Operating Activities

During the Track Record Period, we incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our research and development expenses and administrative expenses. Our management closely monitors the use of cash and cash balances and has maintained a healthy liquidity for our operations. As our business develops and expands, we expect to generate more cash flows from our operating activities, through launching and commercializing our products and enhancing our cost containment capacity and operating efficiency.

In 2022, our net cash used in operating activities was RMB176.7 million, which was primarily attributable to our loss before tax of RMB188.9 million, adjusted for non-cash and non-operating items. Positive adjustments primarily included: (i) an increase in trade and other payables of RMB9.5 million; (ii) depreciation of property and equipment of RMB6.3 million; and (iii) a decrease in value added tax recoverable of RMB5.2 million. Negative adjustments mainly included: (i) an increase in prepayments, deposits and other receivables of RMB7.9 million; and (ii) a decrease in amount due to a related party of RMB4.7 million.

In 2021, our net cash used in operating activities was RMB98.7 million, which was primarily attributable to our loss before tax of RMB148.5 million, adjusted for non-cash and non-operating items. Positive adjustments primarily included: (i) share-based payment expenses of RMB39.6 million; (ii) finance costs of RMB15.0 million; (iii) depreciation of property and equipment of RMB7.0 million; and (iv) an increase in amount due to a related party of RMB3.2 million. Negative adjustments mainly included: (i) an increase in prepayments, deposits and other receivables of RMB8.8 million; and (ii) an increase in value added tax recoverable of RMB6.1 million.

We plan to improve our net operating cash flow position in view of potential net operating cash inflows which we expect to generate after successful commercialization of our product candidates. As our business develops, we expect to improve our negative cash flow position from our operations by generating more net cash from our operating activities, launch our drug candidates and improving our cost control and operating efficiencies.

- We plan to accelerate the clinical development and commercialization of our Core Product, M701, which is currently under phase II clinical trial in China. We expect to complete the Phase II clinical trial of M701 monotherapy in combination with systematic treatment for the treatment of MA in the fourth quarter of 2023. After the completion of this Phase II trial, we plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. To date, there have been no established, evidence-based, universally accepted guidelines in treating MA and MPE globally. M701 is an innovative candidate as an effective targeted therapy for MA and MPE to address this pressing medical need. For more details, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Market Opportunities and Competition” in this document. We expect that

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M701 will be positioned to capture the market opportunities after commercialization and we will be able to improve our net operating cash flow position through the commercialization of M701 in China. In addition, we initiated a Phase Ib/II clinical trial of M701 for the treatment of MPE in China in November 2022. We expect to complete this Phase Ib/II trial and commence a pivotal/Phase III trial for M701 for the treatment of MPE in China in the third quarter of 2024, and file BLA submission in the fourth quarter of 2025, which will also contribute to our cash inflow after the commercialization for MPE treatment.

- We will also advance the research and development, clinical trials and commercialization of other product candidates in our pipeline. For example, we are currently conducting a Phase I clinical trial of Y150 in rrMM in China and expect to complete this trial in the second quarter of 2024. We are also conducting the Phase I clinical trial for Y101D in patients with metastatic or locally advanced solid tumors in China and expect to complete this trial in the fourth quarter of 2023. After these clinical-stage product candidates are approved, we expect we will generate more cash from operating activities through the commercialization of these product candidates.
- We plan to adopt comprehensive measures to more effectively control our cost and operating expenses leveraging our economies of scale. Our object is to optimize liquidity to gain a better return for our Shareholders and maintain adequate risk control. After our drug candidates’ commercialization, we plan to closely monitor and manage the settlement of our trade receivables to avoid credit losses. We will also closely monitor the settlement of our trade payables to achieve better cash flow position.

Investing Activities

In 2022, our net cash from investing activities was RMB5.8 million, which was mainly due to our redemption of financial assets at FVTPL of RMB351.0 million and an advance we received from transfer agreement of RMB33.8 million, which was partially offset by our purchase of financial assets at FVTPL of RMB378.5 million.

In 2021, our net cash used in investing activities was RMB19.9 million, which was mainly due to our purchase of financial assets at FVTPL of RMB481.6 million, which was partially offset by our redemption of financial assets at FVTPL of RMB462.1 million.

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Financing Activities

In 2022, our net cash from financing activities was RMB241.3 million, which was mainly due to the proceeds we received from the issue of shares of RMB200.0 million and the new bank borrowing of RMB76.5 million, which was partially offset by repayment of bank borrowings of RMB28.0 million.

In 2021, our net cash from financing activities was RMB81.0 million, which was mainly due to the various proceeds we received from our equity financings of RMB149.9 million and the new bank borrowing of RMB28.0 million, which was partially offset by repayment of borrowings from shareholders of RMB71.1 million and repayment of bank borrowings of RMB21.0 million.

CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the years indicated:

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Costs Relating to Research and Development of Our Core Product		
Clinical trial costs	5,253	23,093
Raw material and utility expenses	1,092	3,773
Staff costs	1,681	3,084
Others ⁽¹⁾	398	442
Subtotal	8,424	30,392
Costs Relating to Research and Development of Other Drug Candidates		
Clinical trial costs	17,041	35,698
Pre-clinical study costs	21,358	49,794
Raw material and utility expenses	16,504	17,708
Staff costs	15,877	20,327
Others	1,367	1,247
Subtotal	72,147	124,774

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	Year Ended December 31,	
	2021	2022
	(RMB in thousands)	
Workforce employment cost ⁽²⁾	4,765	5,002
Direct production cost ⁽³⁾	—	—
Non-income taxes, royalties and other governmental charges	—	—
Contingency allowances	—	—
Product marketing ⁽⁴⁾	—	—
Total	85,336	160,168

(1) This includes the cash operating costs related to the pre-clinical studies of M701’s treatment of MPE and solid tumor.

(2) Workforce employment cost represents total non-research and development personnel costs mainly including salaries and benefits.

(3) We had not commenced commercial manufacturing as of the Latest Practicable Date.

(4) We had not commenced product sales as of the Latest Practicable Date.

WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account the financial resources available, including cash and bank balances of RMB104.7 million as of April 30, 2023 on hand and the estimated [REDACTED] from the [REDACTED], as well as our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, general and administrative expenses and other operating expenses for at least the next 12 months from the date of this document. After making reasonable enquiries with the Company about the Company’s working capital requirements, nothing has come to the Sole Sponsor’s attention which would cause them to disagree with the Directors’ view above.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including clinical development and business development activities; (ii) purchase of property and equipment; (iii) interest paid; (iv) interest paid on lease liabilities; and (iv) payments of lease liabilities. We had cash and cash equivalents of RMB104.7 million as of April 30, 2023. Assuming an average cash burn rate going forward of 1.0 times of the level in 2022, we estimate that our cash and cash equivalents and financial assets at fair value through profit or loss as of April 30, 2023 will be able to maintain our financial viability for 16 months taking into account the estimated [REDACTED] from the [REDACTED] (based on the low-end of the indicative [REDACTED] range stated in this document). Our Directors and management team will continue to monitor our working capital, cash flows, and our business development progress. We will continue to monitor our cash flows from operations closely and

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expect to raise our next round of financing, if needed, with a minimum buffer of 12 months. In the event our business operations experience any material and adverse impact, we will proactively manage our cash flows and control our costs and expenses; on the other hand, in the event we identify any additional promising research and development projects, or identify any suitable target for investment or acquisition, we may adjust our financing plans to take advantage of such opportunities. We may also diversify our source of funding to further support the development of our product candidates going forward.

Our Directors confirmed that there had been no material defaults in payment of trade and other payables during the Track Record Period and up to the date of the Latest Practicable Date.

INDEBTEDNESS

As of December 31, 2021 and 2022, and April 30, 2023, except as disclosed in the tables below, we did not have any outstanding 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. During the Track Record Period, we had indebtedness in the form of interest-bearing bank borrowings and lease liabilities. The following table sets forth a breakdown of our indebtedness as of the dates indicated:

	As of December 31,		As of
	2021	2022	April 30,
			2023
	<i>(RMB in thousands)</i>		<i>(unaudited)</i>
Current			
Bank borrowings	28,000	76,500	49,000
Lease liabilities	397	169	331
Non-current			
Lease liabilities	83	–	438
Total	28,480	76,669	49,769

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Bank borrowings

During the Track Record Period, our bank borrowings consisted of secured bank loans and unsecured bank loans. As of the Latest Practicable Date, none of our bank loans were backed or guaranteed by any of our substantial Shareholders. The following table sets forth a breakdown of our bank borrowings as of the dates indicated:

	As of December 31,		As of April 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		<i>(unaudited)</i>
Secured bank loans	23,000	45,000	45,000
Unsecured bank loans	5,000	31,500	4,000
	<u>28,000</u>	<u>76,500</u>	<u>49,000</u>

The carrying amounts of the above borrowings are repayable within one year. We have fully repaid the outstanding amount of the bank borrowings as of December 31, 2021. The outstanding amount of the bank borrowings as of December 31, 2022 and as of April 30, 2023 was related to (i) bank borrowings of RMB45.0 million that carried a fixed-rate interest rate (also being the effective interest rate) of 4.35% per annum, of which RMB18.0 million has been repaid in May 2023 and the rest will be repayable in full in June and July 2023, and were secured by our property and equipment, right-of-use assets and investment properties with carrying amount of RMB6.6 million, RMB8.3 million, and RMB0.5 million, respectively, as of December 31, 2022; and (ii) bank borrowings of RMB4.0 million that carried a fixed-rate interest rate (also being the effective interest rate) of 5.10% per annum, which will be repayable in full in June 2023.

Our bank borrowings agreements contain standard terms, conditions and covenants that are customary for commercial bank loans. Our Directors confirm that we had not experienced any difficulty in obtaining bank borrowings, default in payment of bank borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date. As of the Latest Practicable Date, we had unutilized banking facilities of RMB280 million.

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Lease liabilities

The following table sets forth our lease liabilities as of the dates indicated:

	As of December 31,		As of
	2021	2022	April 30,
			2023
	(RMB in thousands)		(unaudited)
Lease liabilities			
Current	397	169	331
Non-current	83	–	438
Total	480	169	769

At the commencement date of a lease, we recognize and measure lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, we use the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. The weighted average incremental borrowing rates applied to lease liabilities is 5.72% to 5.90% per annum for the Track Record Period.

CAPITAL EXPENDITURES

We regularly incur capital expenditures to purchase and maintain our property and equipment in order to enhance our research and development capabilities and expand our business operations. Historically, we funded our capital expenditures mainly through equity financing. The following table sets forth our capital expenditures for the years indicated:

	Year Ended December 31,	
	2021	2022
	(RMB in thousands)	
Purchases of property and equipment	1,757	1,363

Our historical capital expenditures during the Track Record Period primarily included expenditures associated with the purchase of property and equipment, which mainly consists of furniture and equipment and leasehold improvements. Going forward, we expect that our capital expenditure will continue to consist primarily of funds to ramp up the research and development of our product candidates, and purchases of machinery and equipment for our offices and research and development facilities. For more details, please refer to the section headed “Future Plans and [REDACTED]” in this document.

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CONTRACTUAL OBLIGATIONS

Capital Commitments

As of December 31, 2021 and 2022, we did not have any significant capital commitments.

CONTINGENT LIABILITIES

As of December 31, 2021 and 2022, we did not have any contingent liabilities. As of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

RELATED-PARTY TRANSACTIONS

For the years ended December 31, 2021 and 2022, our related party transactions mainly comprised of: (i) interest expenses arising from borrowings from related parties; (ii) purchase of research and development service from a related party; (iii) outstanding balances with related parties; and (iv) compensation of key personnel. For further details, please refer to Notes 25 and 32 to the Accountants’ Report in Appendix I to this document.

Our Directors believe that our transactions with the related parties during the Track Record Period were conducted on an arm’s length basis, and they did not distort our results of operations or make our historical results not reflective of our future performance.

KEY FINANCIAL RATIOS

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

	As of December 31,	
	2021	2022
Current ratio ⁽¹⁾	2.2	1.6

(1) Current ratio is calculated by current assets divided by current liabilities as of the same date.

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Current Ratio

Our current ratio decreased from 2.2 as of December 31, 2021 to 1.6 as of December 31, 2022, primarily due to an increase in our current liabilities, which outpaced an increase in our current assets, mainly as a result of: (i) an increase in bank borrowings by RMB48.5 million for the year ended December 31, 2022; (ii) an increase in advance from transfer agreement by RMB33.8 million for the year ended December 31, 2022; and (iii) an increase in trade and other payables by RMB10.9 million for the year ended December 31, 2022.

MARKET RISK DISCLOSURE

The risks associated with our financial assets and liabilities primarily include market risks (currency risk and interest rate risk), credit risk and liquidity risk. Our Directors manage these exposures to ensure appropriate measure are implemented on a timely and effective manner. Please refer to Note 36 to the Accountants’ Report in Appendix I to this document for further details.

Currency Risk

Certain of our financial liabilities are denominated in foreign currency of respective group entities which expose us to foreign currency risk. We did not have a foreign currency hedging policy against our exposure to currency risk during the Track Record Period and up to the Latest Practicable Date. However, our Directors monitor foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise. For details, including relevant sensitivity analysis, please refer to Note 36(b)(i) to the Accountants’ Report set out in Appendix I to this document.

Interest Rate Risk

We are primarily exposed to fair value interest rate risk in relation to bank borrowings, amounts due to shareholders, lease liabilities and cash flow interest rate risk in relation to bank balances. We did not have an interest rate hedging policy to mitigate interest rate risk during the Track Record Period and up to the Latest Practicable Date. However, our Directors monitor interest rate exposure and will consider hedging significant interest rate risk should the need arise.

Credit Risk

Our maximum exposure to credit risk, which will cause a financial loss to the Group, arises from the amount of each class of financial assets (including deposits and other receivables, amount due from a subsidiary, and bank balances) as disclosed in the consolidated statements of financial position. During the Track Record Period and up to the Latest Practicable Date, we did not hold any collateral or other credit enhancements to cover credit risks associated with our financial assets.

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Deposits and other Receivables

For deposits and other receivables, we have applied the 12-month expected credit loss (ECL) approach in IFRS 9 to measure the loss allowance. The ECL on other receivables are assessed individually based on historical settlement records and past default experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current as well as the forecast direction of conditions at the end of each reporting period. Our Directors consider the ECL provisions of other receivables as insignificant.

Amount due from a subsidiary

For amount due from a subsidiary, we have applied 12-month ECL to measure the loss allowance. In assessing the probability of defaults of amount due from a subsidiary, our Directors have taken into account the financial position of the counterparty as well as forward looking information that is available without undue cost or effort. Our Directors consider the ECL provision of amount due from a subsidiary as insignificant.

Bank Balances

Our credit risk on bank balances is limited because the counterparties are reputable financial institutions. Our Directors are of the view that the average loss rate is insignificant and no impairment was provided at the end of each reporting period.

Liquidity Risk

With respect to the management of liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by the management to finance our operations and mitigate the effect of fluctuations in cash flows. We monitor the utilization of bank borrowings and rely on the issuance of Investors’ Shares and ordinary shares as a significant source of liquidity. Our Directors are satisfied that we will have sufficient financial resources to meet our financial obligations as they fall due and to sustain our operations for the foreseeable future. For details, please refer to Note 36(b) to the Accountants’ Report set out in Appendix I to this document.

DIVIDEND

We did not declare or pay any dividend during the Track Record Period. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. Regulations in the PRC currently

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permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, as determined in accordance with its articles of association and the accounting standards and regulations in China. As a result, we may not have sufficient or any distributable profits to make dividend contributions to our Shareholders, even if we become profitable.

DISTRIBUTABLE RESERVES

As of December 31, 2022, we did not have any distributable reserves.

[REDACTED] EXPENSE

[REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (including [REDACTED], based on the mid-point of our indicative [REDACTED] for the [REDACTED]), assuming no Shares are [REDACTED] pursuant to the [REDACTED] Option. During the Track Record Period, we incurred [REDACTED] expenses of approximately RMB[REDACTED], among which RMB[REDACTED] was recognized in our consolidated statements of profit or loss and other comprehensive income, and approximately RMB[REDACTED] ([REDACTED] expenses directly attributable to the [REDACTED] of Shares) will be deducted from equity upon [REDACTED]. After December 31, 2022, approximately RMB[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] is expected to be charged against equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

The [REDACTED] expenses are expected to represent approximately [REDACTED] of the [REDACTED] of the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED] range) and that the [REDACTED] is not exercised. The [REDACTED] expenses are comprised of: (i) [REDACTED] expenses of RMB[REDACTED]; and (ii) [REDACTED] expenses of RMB[REDACTED], which can be further broken down into: (A) fees and expenses of legal advisors and accountants of RMB[REDACTED]; and (B) other fees and expenses of RMB[REDACTED].

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[REDACTED]

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[REDACTED]

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, there has been no material adverse change in our financial or trading position or prospects since December 31, 2022 and up to the date of this document and there is no event since December 31, 2022 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

IMPACT OF THE COVID-19 OUTBREAK

Since late 2019, COVID-19 has spread rapidly globally. Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 cases in several parts of China due to the spread of the Omicron variant. We have employed various measures to mitigate any impact the COVID-19 pandemic may have on our operations, including offering personal protection equipment such as masks to our employees, regularly checking the body temperature of our employees and closely monitoring their health conditions.

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The COVID-19 outbreak and resurgences in China and the quarantine measures taken by the PRC government had only limited impact on us. From early 2020 to December 2022, we experienced increased difficulties in patient enrollment for the Phase I and Phase II clinical trials of M701 for the treatment of MA. Specifically, for the Phase II clinical trial of M701 for the treatment of MA, we originally planned to have the first patient in October 2021 and expected to enroll eight to ten patients per month. However, due to the lockdown measures implemented by local governments where our research institutions are located, we did not have our first patient in until December 2021 and the number of patients enrolled in the Phase II clinical trial of M701 for the treatment of MA was approximately six per month from December 2021 to April 2022, lower than what we originally expected. The above disruptions in combined, lead to certain delays in advancing the clinical development of M701 and relatively lower R&D expenses for M701 during the Track Record Period. We also experienced temporary delays in subject enrollment for our clinical trials in certain regions, such as Beijing, Shanghai and Henan province, for one to three months in 2022. Nevertheless, we resumed the normal patient enrollment for these clinical trials later, and the resurgences and quarantine measures did not cause any material impact on our clinical trials, including any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We employed various measures to mitigate any impact the COVID-19 outbreak and resurgences may have on our ongoing clinical trials in China, including providing alternative methods for safety and efficacy assessment, continuing patient visit through remote access, and engaging necessary communications with our investigators to identify and address any issues that may arise. The expected development progress of our drug candidates has taken into account the temporary delays and disruptions on our ongoing clinical trials caused by the COVID-19 resurgences. With regard to the impact of the resurgence of COVID-19 outbreak since December 2022, most of our employees were infected with COVID-19, and then recovered within a short period of time. Our operations for clinical trials experienced disruptions, however, such delays were temporary and we resumed the normal patient enrollment since January 2023. For example, the number of patients we enrolled for all of our ongoing clinical trials increased from eight in January 2023 to eleven in February 2023, and further to 16 patients in March 2023, among which we enrolled three, seven and ten patients for clinical trials of M701 in January, February and March 2023, respectively. In addition, as such resurgence was less severe because of lower mortality rate and higher curability rate than that of the initial COVID-19 outbreak in early 2020, and taking into account that the COVID-19 related governmental measures have been gradually lifted in China (such as the government’s releasing measures to lift up quarantine measures and travel restrictions to accelerate the economic recovery and resume normal operations of the society), our Directors were not aware of any material adverse impact of such resurgence on our operations and financial performance.

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Although the COVID-19 related restrictive measures adopted by the Chinese government were lifted in various regions in China since December 2022, it is still uncertain whether the continuance or future recurrence of the COVID-19 outbreak in China will have a material adverse effect on our business, results of operations, financial position or prospects. The recent COVID-19 outbreaks in China, and future resurgences, if any, may adversely affect our operations if any of our employees or employees of our suppliers and other business partners are suspected of contracting or contracted COVID-19, as we, our suppliers or our business partners may arrange such employees to work remotely at home or disinfect the operating facilities. The ongoing clinical trials and the commencement of new clinical trials for our drug candidates could also be delayed if, due to the COVID-19 outbreak and resurgences in China, there is any delay or failure in subject recruitment or enrollment and/or any diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials from the conduct of clinical trials.

In view of the above situation, our Directors confirm that the COVID-19 outbreak did not have a material adverse impact on our business operations and financial performance as of the Latest Practicable Date, as (i) there had been no material disruption of our ongoing clinical trials or research and development efforts; and (ii) we had not encountered any material supply chain disruption and had not experienced any material difficulties in procuring major raw materials.

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. We cannot foresee whether COVID-19 will have a material and adverse impact on our business going forward. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We face risks related to health epidemics and other outbreaks of contagious diseases, including the COVID-19 outbreak” in this document. We will closely monitor and evaluate any impact of the COVID-19 outbreak and resurgences on us and adjust our precautionary measures according to its developments.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

OVERVIEW

The Board currently consists of 14 Directors, including one executive Director, eight non-executive Directors and five independent non-executive Directors. The Directors serve for a term of three years and shall be subject to re-election upon retirement. The Board is responsible for and has the general power over the management and operation of our business, including determining our business strategies and investment plans, implementing resolutions passed at our general meetings, and exercising other powers, functions and duties as conferred by the Articles of Association. The Board also assumes the responsibilities for developing and reviewing the policies and practices of the Company on corporate governance, risk management, internal control and compliance with legal and regulatory requirements.

The Supervisory Committee currently consists of five Supervisors. The Supervisory Committee is responsible for supervising the performance of duty of the Board and the senior management of the Company and overseeing the financial, internal control and risk conditions of the Company.

The senior management currently consists of five members who are responsible for our day-to-day management and operation.

DIRECTORS

The following table sets forth the key information about the Directors.

Name	Age	Position	Responsibilities	Date of the first appointment as a Director	Date of joining the Group
Dr. Zhou Pengfei	56	Co-founder of the Group, chairman of the Board, executive Director, and chief executive officer	Responsible for the overall strategic planning of the Group and supervises and oversees the management of our business	October 8, 2014	July 8, 2010
Yuan Qian (袁謙)	56	Co-founder of the Group and non-executive Director	Responsible for participating in the formulation of the general corporate business plans, strategies and major decisions of the Group through the Board	July 8, 2010	July 8, 2010

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Responsibilities	Date of the first appointment as a Director	Date of joining the Group
Dr. Zhou Hongfeng (周宏峰)	53	Co-founder of the Group and non-executive Director	Responsible for participating in the formulation of the general corporate business plans, strategies and major decisions of the Group through the Board	July 8, 2010	July 8, 2010
Pang Zhenhai (龐振海)	48	Non-executive Director	Responsible for providing guidance and advice on corporate and business strategies	January 10, 2020	January 10, 2020
Dr. Hui Xiwu (惠希武)	38	Non-executive Director	Responsible for providing guidance and advice on corporate and business strategies	September 26, 2022	September 26, 2022
Liang Qian (梁倩)	50	Non-executive Director	Responsible for providing guidance and advice on corporate and business strategies	January 10, 2018	January 10, 2018
Dr. Liu Dan (柳丹)	39	Non-executive Director	Responsible for providing guidance and advice on corporate and business strategies	September 26, 2022	September 26, 2022
Dr. Guo Hongwei (郭宏偉)	55	Non-executive Director	Responsible for providing guidance and advice on corporate and business strategies	November 24, 2020	January 5, 2021

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Responsibilities	Date of the first appointment as a Director	Date of joining the Group
Xie Shouwu (謝守武)	39	Non-executive Director	Responsible for providing guidance and advice on corporate, business strategies and financial position	September 26, 2022	September 26, 2022
Dr. Cheng Bin (程斌)	56	Independent non-executive Director	Responsible for supervising and providing independent judgment to the Board	[REDACTED]	[REDACTED]
Dr. Dai Weiguo	59	Independent non-executive Director	Responsible for supervising and providing independent judgment to the Board	[REDACTED]	[REDACTED]
Fu Lili (付黎黎)	38	Independent non-executive Director	Responsible for supervising the Group’s financial position and providing independent judgment to the Board	[REDACTED]	[REDACTED]
Dr. Deng Yuezhen (鄧躍臻)	43	Independent non-executive Director	Responsible for supervising and providing independent judgment to the Board	[REDACTED]	[REDACTED]
Dr. Chen Bin (陳斌)	61	Independent non-executive Director	Responsible for supervising and providing independent judgment to the Board	[REDACTED]	[REDACTED]

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Executive Director

Dr. Zhou Pengfei, aged 56, the co-founder of the Group, was appointed as a Director of the Company in October 2014, as the chief executive officer of the Company in March 2018, and as the chairman of the Board in September 2022. He was later re-designated as the executive Director in November 2022. He is responsible for the overall strategic planning of the Group and supervises and oversees the management of our business. He also serves as the general manager of all of our subsidiaries, namely Nanjing Youbodi, Shijiazhuang Shiyou and Wuhan Youwei, respectively.

Dr. Zhou has over 33 years of experience in the healthcare and pharmaceutical industries. After completion of undergraduate studies, Dr. Zhou successively served as a physician at the pediatrics department and the general surgery department of Shenzhen Second People's Hospital (深圳第二人民医院) (previously known as Shenzhen Red Cross Hospital (深圳市紅十字會醫院)). He served as a postdoctoral research fellow in microbiology and immunology in the School of Medicine of Stanford University in the U.S. from May 2005 to January 2006 and later served in Schering-Plough Corporation. Prior to founding the Group in July 2010, he worked at Crown Bioscience (Beijing) Co., Ltd. (中美冠科生物技術(北京)有限公司), a subsidiary of Crown Bioscience International (a company previously listed on the Taipei Stock Exchange (stock code: KY(6554))) from September 2008 to June 2010, with last position as executive director. He was appointed as a director and the vice-chairman of the board of directors of Wuhan YZY Medical Science and Technology Co., Ltd. (武漢友芝友醫療科技股份有限公司) (a company controlled by Yuan Qian and primarily engaged in the sales of medical device, which does not compete and is unlikely to compete, directly or indirectly, with the Company's business) in July 2011 and March 2017, respectively. He has also served as a visiting professor at Tongji Medical College of Huazhong University of Science and Technology (華科技大學同濟醫學院) since January 2012, and a visiting professor at Central South University (中南大學) in the PRC since April 2022.

Dr. Zhou obtained a bachelor's degree in pediatrics in June 1989, and a master's degree in pediatric surgery (oncology) in June 1994, respectively, from Tongji Medical University (同濟醫科大學) (currently known as Tongji Medical College of Huazhong University of Science and Technology) in the PRC. He also obtained a doctorate in medicine from McMaster University in Canada in November 2005.

Dr. Zhou was recognized as a senior engineer by Hubei Professional Title Reform Leading Group Office (湖北省職稱改革工作領導小組辦公室) in December 2018. He has also served as the president of the Biopharmaceuticals Industry Association of Wuhan East Lake National Innovation Demonstration Zone (武漢東湖國家自主創新示範區生物醫藥行業協會) since May 2022 and a supervisor in the National Postdoctoral Research Workstation (國家博士後科研工作站) since October 2018.

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Non-executive Directors

Yuan Qian (袁謙), aged 56, the co-founder of the Group, was appointed as a Director in July 2010 and re-designated as a non-executive Director in November 2022. He was also the chairman of the Board from July 2010 to January 2018 and the chief executive officer of the Company from July 2010 to March 2018. The completion of the Series A Financing in 2018 saw the Company’s entry into a new phase of development. Considering CSPC, being a prominent pharmaceutical company in China, had become a substantial shareholder of the Company and Dr. Zhou Pengfei’s rich clinical research and management experience had proven to be crucial to the Group’s achievements and future development, Mr. Yuan stepped down from the positions of chairman of the Board and the chief executive officer of the Company while CSPC nominated the chairman of the Board. Mr. Yuan perceived such change as instrumental to enhance the Board’s industrial expertise and competencies and improve the Company’s corporate governance. The change in Mr. Yuan’s executive roles, having not concerned any of his integrity, competency or suitability as a chairman of the Board or a chief executive officer of the Company, did not result in any movement of key R&D personal of the Core Product, nor had any material impact on the Group’s the business and R&D operations. Mr. Yuan remains involved in the formulation of the general corporate business plans, strategies, and major decisions of the Group through the Board.

Prior to founding the Group, Mr. Yuan founded and held positions in several corporates covering various business areas, including Hubei Zhiyou Mechatronics Co., Ltd. (湖北芝友機電工程有限公司) (a company controlled by Mr. Yuan and primarily engaged in construction business, which does not compete and is unlikely to compete, directly or indirectly, with the Company’s business) where he has served as an executive director since October 1995, YZY Industrial Group Co., Ltd. (友芝友實業集團有限公司) (a company wholly owned by Mr. Yuan and primarily engaged in aquaculture business, which does not compete and is unlikely to compete, directly or indirectly, with the Company’s business) where he has served as an executive director and the general manager since November 1999, Wuhan YZY Industrial Development Co., Ltd. (武漢友芝友產業發展有限公司) (a company controlled by Mr. Yuan and primarily engaged in business consulting services, which does not compete and is unlikely to compete, directly or indirectly, with the Company’s business) where he has served as an executive director since March 2002, and Wuhan YZY Medical Science and Technology Co., Ltd. (武漢友芝友醫療科技股份有限公司) where he has served as a director and the chairman of the board since July 2011.

Mr. Yuan obtained a bachelor’s degree in clinical medicine from Tongji Medical University (同濟醫科大學) (currently known as Tongji Medical College of Huazhong University of Science and Technology) in June 1990 and a master’s degree of business administration from China Europe International Business School (中歐國際工商學院) in the PRC in September 2007, respectively. He is currently a candidate of the global finance GFD program at Tsinghua University PBC School of Finance (清華大學五道口金融學院) in the PRC.

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Dr. Zhou Hongfeng (周宏峰), aged 53, the co-founder of the Group, was appointed as a Director in July 2010 and re-designated as a non-executive Director in November 2022. He is currently responsible for participating in the formulation of the general corporate business plans, strategies and major decisions of the Group through the Board.

Dr. Zhou served as a lecturer at the School of Public Health of Sun Yat-Sen Medical University (中山醫科大學公共衛生學院) (currently known as Zhongshan School of Medicine of Sun Yat-Sen University (中山大學中山醫學院)), from July 1992 to August 1998. He then served in a management position of Guangdong Yikangda Technology Development Co., Ltd. (廣東怡康達科技發展有限公司) from April 2002 to June 2010, and the chairman of the board of Guangdong Huakai Investment Co., Ltd. (廣東鐸凱投資有限公司) from June 2007 to July 2014. He has also served as the co-founder and a director of Wuhan YZY Medical Science and Technology Co., Ltd. (武漢友芝友醫療科技股份有限公司) since July 2011.

Dr. Zhou obtained a bachelor's degree in medicine in June 1992 from Tongji Medical University (同濟醫科大學) (currently known as Tongji Medical College of Huazhong University of Science and Technology). He then obtained a master's degree in medicine in December 1997 from Sun Yat-Sen Medical University (中山醫科大學) (currently known as Zhongshan School of Medicine of Sun Yat-Sen University (中山大學中山醫學院)). He also obtained a master's degree of business administration in March 2014 from the Carlson School of Management, the University of Minnesota in the U.S. and a doctorate in social medicine and health administration in December 2014 from Huazhong University of Science and Technology (華中科技大學) in the PRC. He is currently a candidate for an EMBA degree at Tsinghua University PBC School of Finance (清華大學五道口金融學院).

Pang Zhenhai (龐振海), aged 48, was appointed as a Director in January 2020 and re-designated as a non-executive Director in November 2022. He is responsible for providing guidance and advice on corporate and business strategies.

Mr. Pang worked at Shijiazhuang No. 2 Pharmaceutical Factory (石家莊市第二製藥廠) from October 1999 to February 2001. He then successively served as a budget supervisor and a capital manager at the finance department of CSPC Holdings Company Limited (石藥控股集團有限公司) from March 2001 to March 2005, a manager at purchasing department of CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. (石藥集團中諾藥業(石家莊)有限公司) from April 2005 to June 2009, a senior director at investment and strategic planning department of CSPC Holdings Company Limited from July 2009 to February 2012, a deputy general manager of CSPC Zhongcheng Medicines Co., Ltd. (石藥集團中誠醫藥有限公司) from March 2012 to August 2014, a general director at the finance department of CSPC (a company listed on the Stock Exchange (stock code: 1093)) from September 2014 to June 2015, and a senior director at capital operation center of CSPC Group from July 2015 to December 2020. Mr. Pang has served as a director of Shanghai Shifengxinhui Venture Capital Management Co., Ltd. (上海石豐昕匯創業投資管理有限公司) since July 2019, and a director at business development department of CSPC Group since December 2020.

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Mr. Pang obtained a bachelor’s degree in accounting from Lanzhou University (蘭州大學) in the PRC in July 1999.

Dr. Hui Xiwu (惠希武), aged 38, was appointed as a Director in September 2022 and re-designated as a non-executive Director in November 2022. He is responsible for providing guidance and advice on corporate and business strategies.

Dr. Hui successively served as a researcher from July 2012 to October 2015, an office director from November 2015 to September 2017, and a deputy director of the research institute from October 2017 to September 2019, at CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd. (石藥集團中奇製藥技術(石家莊)有限公司). He then served as a director of the research institute of CSPC Jushi Biopharmaceutical Co., Ltd. (石藥集團巨石生物製藥有限公司) from October 2019 to September 2022.

Dr. Hui obtained a bachelor’s degree in bioscience from Yantai University (煙臺大學) in the PRC in June 2006. He then obtained his doctorate in biochemistry and molecular biology through the successive postgraduate and doctoral program from Peking Union Medical College (北京協和醫學院) in the PRC in July 2012.

Liang Qian (梁倩), aged 50, was appointed as a Director in January 2018 and re-designated as a non-executive Director in November 2022. She is responsible for providing guidance and advice on corporate and business strategies.

Ms. Liang possesses extensive experience in the development and manufacture of genetic recombinant drugs. She served as a technological researcher at North China Pharmaceutical Group New Drug R&D Co., Ltd. (華北製藥集團新藥研究所) from July 1996 to October 1998 and appointed as a development manager at NCPC Genetech Biotechnology Co., Ltd. (華北製藥金坦生物技術股份有限公司) in October 1998. She also served as the executive director at Dali Shangguanhua Tourism Co., Ltd. (大理市上關花旅遊有限公司) from September 2012 to June 2022.

Ms. Liang obtained a bachelor’s degree in chemical engineering from Hebei University of Technology (河北工業大學) in the PRC in July 1996 and a master’s degree in pharmaceutical science from Hebei Medical University (河北醫科大學) in the PRC in June 2009.

Dr. Liu Dan (柳丹), aged 39, was appointed as a Director in September 2022 and re-designated as a non-executive Director in November 2022. He is responsible for providing guidance and advice on corporate and business strategies.

Dr. Liu served as an associate consultant at Bain Chuangxiao Management Consulting (Shanghai) Co., Ltd. (貝恩創效管理諮詢(上海)有限公司) from January 2014 to October 2015. He has served as a senior partner at CDH Equity Investment Management (Tianjin) Co., Ltd. (鼎暉股權投資管理(天津)有限公司) since October 2015.

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Dr. Liu currently holds various positions outside of the Group. He has served as an independent director of Jiangsu Hualan New Pharmaceutical Material Co., Ltd. (江蘇華蘭藥用新材料股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 301093)) since October 2018, a director of GemPharmatech Co., Ltd. (江蘇集萃藥康生物科技股份有限公司) (a company listed on the Shanghai Stock Exchange Science and Technology Innovation Board (stock code: 688046)) since May 2019, and a supervisor of HitGen Inc. (成都先導藥物開發股份有限公司) (a company listed on the Shanghai Stock Exchange Science and Technology Innovation Board (stock code: 688222)) since May 2022.

Dr. Liu obtained a bachelor's degree in biotechnology in July 2006 from Nanjing University School of Life Science (南京大學生命科學學院) in the PRC. He also graduated from a joint program of Vanderbilt University and Yale University in the U.S., obtaining a doctorate in cancer biology issued by Vanderbilt University in November 2012. He completed postdoctoral training in the Department of Surgery, Yale University in the U.S. from November 2012 to December 2013. He was certified as a securities investment fund practitioner by the Asset Management Association of China (中國證券投資基金業協會) in September 2017.

Dr. Guo Hongwei (郭宏偉), aged 55, was appointed as a Director in November 2020 and re-designated as a non-executive Director in November 2022. He is responsible for providing guidance and advice on corporate and business strategies.

Dr. Guo has extensive work experience in financial and investment sector. Prior to joining the Group, he worked at the People's Bank of China (中國人民銀行) from July 1993 to September 2003. From September 2003 to April 2010, he worked at China Banking Regulatory Commission (中國銀行業監督管理委員會) (currently known as China Banking and Insurance Regulatory Commission (中國銀行保險監督管理委員會)). He also worked at Bank of Communications Co., Ltd. (交通銀行股份有限公司) (a company listed on the Stock Exchange (stock code: 3328) and the Shanghai Stock Exchange (stock code: 601328)) from April 2010 to March 2017. From April 2017 to April 2018, he worked at Beijing Hualian Department Store Co., Ltd. (北京華聯商厦股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 000882)) with last position as the vice-chairman of the board. He then served as the president of Zhongbang Jinkong Investment Co., Ltd. (眾邦金控投資有限公司) from April 2018 to December 2020. He has also served as the chairman of the board of directors of Tongde Qianyuan (Beijing) Investment Management Co., Ltd. (同德乾元(北京)投資管理有限公司) since August 2021.

Dr. Guo currently holds directorships in various companies. He has served as an independent non-executive director of Kunlun Financial Leasing Co., Ltd. (昆侖金融租賃有限責任公司) since October 2019, an independent non-executive director of Junkang Life Insurance Co., Ltd. (君康人壽保險股份有限公司) since May 2020, and an independent non-executive director of Sanxiang Impression Co., Ltd. (三湘印象股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 000863)) since July 2021.

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Dr. Guo obtained a bachelor’s degree and a master’s degree in economics from Renmin University of China (中國人民大學) in the PRC in July 1990 and July 1993, respectively. He also obtained a doctorate in economics in July 2004 from Renmin University of China. He was certified as a private equity investment fund practitioner by the Asset Management Association of China (中國證券投資基金業協會) in September 2017. He also passed the Paper 1 (Fundamentals of Securities and Futures Regulation) of the Hong Kong licensing examination for securities and futures intermediary in March 2022.

Xie Shouwu (謝守武), aged 39, was appointed as a Director in September 2022 and re-designated as a non-executive Director in November 2022. He is responsible for providing guidance and advice on corporate, business strategies and financial position.

Mr. Xie worked at Yunnan Yuntianhua Co., Ltd. (雲南雲天化股份有限公司) from July 2007 to April 2011. He later served as an auditor of Wuhan Kaidi Holding Investment Co., Ltd. (武漢凱迪控股投資有限公司) from May 2011 to May 2016. He also established an employment relationship with Kaidi Ecological Environment Technology Co., Ltd. (凱迪生態環境科技股份有限公司) in May 2016. From April 2019 to August 2019, he served as a manager of the audit department of Wuhan Meilian Real Estate Co., Ltd. (武漢美聯地產有限公司). He also began to work at Wuhan Ease Lake New Technology Development Zone Development Co., Ltd. (武漢東湖新技術開發區發展總公司), a wholly-owned subsidiary of Wuhan Hi-tech Holding Group Co., Ltd. (武漢高科國有控股集團有限公司) in August 2019 and was appointed as the deputy executive manager of the audit department of Wuhan Hi-tech Holding Group Co., Ltd. in November 2019.

Mr. Xie obtained a bachelor’s degree in management from Nanjing Audit University (南京審計大學) in the PRC in June 2007. He has been an auditor recognized 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) and the National Audit Office of the PRC (中華人民共和國審計署) since October 2018. He has also been a certified internal auditor recognized by the Institute of Internal Auditors since September 2019.

Independent Non-executive Directors

Dr. Cheng Bin (程斌), aged 56, was elected as an independent non-executive Director on November 11, 2022 and such appointment will be effective from the [REDACTED]. He is responsible for supervising and providing independent judgment to the Board.

Dr. Cheng has engaged in clinical work for more than 20 years and has accumulated rich clinical experience. He has served at the gastroenterology department of Tongji Hospital Affiliated to Tongji Medical College of Huazhong University of Science and Technology (華南科技大學同濟醫學院附屬同濟醫院) since July 1994, with his current positions as a chief physician and a professor.

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Dr. Cheng currently holds positions in the following medical associations:

Association name	Position	Date of appointment
Chinese Medical Association (中華醫學會)	Member of pancreatic disease group of gastroenterology branch	September 2018
	Member of ultrasound endoscopy group of gastrointestinal endoscopy branch	October 2019
China Anti-cancer Association (中國抗癌協會)	Member of oncology endoscopy committee and vice chairman of ultrasound endoscopy group	November 2020
Hubei Association of Pathophysiology (湖北省病理生理學會)	Chairman of digestive specialty committee	December 2020
Hubei Medical Association (湖北省醫學會)	Vice chairman of the society of digestive diseases	December 2020

Dr. Cheng obtained a bachelor’s degree and a master’s degree in medicine from Tongji Medical University (同濟醫科大學) (currently known as Tongji Medical College of Huazhong University of Science and Technology) in June 1989 and June 1994, respectively. He also obtained a medical doctorate in January 2002 from the University of Bonn in Germany. In April 2001, Dr. Cheng obtained the PRC practicing certificate of medical practitioner (執業醫師執業證書) from Hubei Provincial Department of Health (湖北省衛生廳) and the qualification of chief physician from Wuhan Health and Family Planning Commission (武漢市衛生和計劃生育委員會) (currently known as Wuhan Municipal Health Commission (武漢市衛生健康委員會)). He then obtained the PRC medical practitioner qualification certificate (執業醫師資格證書) from Hubei Provincial Department of Health in December 2012.

Dr. Dai Weiguo, aged 59, was elected as an independent non-executive Director on November 11, 2022 and such appointment will be effective from the [REDACTED]. He is responsible for supervising and providing independent judgment to the Board.

Dr. Dai successively served as a research scientist at Amgen Inc. (a company listed on the NASDAQ (stock code: AMGN)) from September 1997 to February 2003, the director of drug product development of the global biologics development at Janssen R&D US (a division of Johnson & Johnson) (commended to be a Janssen Fellow in June 2012) from March 2003 to March 2019, and the vice president of Livzon Pharmaceutical Group Inc. (麗珠醫藥集團股份有限公司) (a company listed on the Stock Exchange (stock code: 1513) and Shenzhen Stock Exchange (stock code: 000513)) from March 2019 to May 2020. He has served as the general

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manager and director of Livzon MABPharm Inc. (珠海市麗珠單抗生物技術有限公司) since April 2019. He has also held the positions of chief executive officer and chairman of the board of directors at Beijing Menlo Biotech Ltd. (北京門羅生物科技股份有限公司) since October 2020.

Dr. Dai obtained a bachelor’s degree and a master’s degree in engineering from Chengdu University of Science and Technology (成都科技大學) (currently known as Sichuan University (四川大學)) in the PRC in July 1983 and June 1986, respectively. Dr. Dai also obtained a doctorate in chemical engineering in May 1997 from the Johns Hopkins University in the U.S.

Fu Lili (付黎黎), aged 38, was elected as an independent non-executive Director on November 11, 2022 and such appointment will be effective from the [REDACTED]. She is responsible for supervising the Group’s financial position and providing independent judgment to the Board.

Ms. Fu has over 13 years of experience in investment, professional accounting and financial consulting. She has also served as an executive director at the investment department of Abax Global Capital (Hong Kong) Limited since June 2013 and a director at Zhejiang Province Salt Industry Group Co., Ltd. (浙江省鹽業集團有限公司) since May 2020.

Ms. Fu obtained a master’s degree in applied statistics in November 2008 from the University of Oxford in the U.K. She is currently a candidate for an executive master in public administration at Tsinghua University (清華大學). She passed the United States Certified Public Accountant Examination in 2011.

Dr. Deng Yuezhen (鄧躍臻), aged 43, was elected as an independent non-executive Director on November 11, 2022 and such appointment will be effective from the [REDACTED]. He is responsible for supervising and providing independent judgment to the Board.

Dr. Deng successively served as an assistant researcher, a postdoctoral fellow and an associate researcher at Shanghai Institutes for Biological Sciences Institute of Nutritional Sciences (上海生命科學研究院營養科學研究所) from May 2009 to April 2012. From September 2017 to September 2022, he served as a researcher at National Clinical Molecular Medicine Research Center (Xiangya Hospital of Central South University) (中南大學湘雅醫院分子醫學研究中心). Dr. Deng has served as a researcher at Shanghai Chest Hospital (上海市胸科醫院) (also known as Thoracic Oncology Institute of Shanghai Chest Hospital of Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院附屬胸科醫院胸部腫瘤研究所)) since September 2022.

Dr. Deng obtained a bachelor’s degree in biotechnology from Wuhan University (武漢大學) in the PRC in June 2004. He then obtained his doctorate in biochemistry and molecular biology through the successive postgraduate and doctoral program from Shanghai Institutes for Biological Sciences of Chinese Academy of Sciences (中國科學院上海生命科學研究院) in

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July 2009. In November 2013, he obtained the Category A qualification of Shanghai Young Science and Technology Rising Star Talent Program (上海市青年科技啟明星人才計劃) issued by Science and Technology Commission of Shanghai Municipality (上海市科學技術委員會).

Dr. Chen Bin (陳斌), aged 61, was elected as an independent non-executive Director on November 11, 2022 and such appointment will be effective from the [REDACTED]. He is responsible for supervising and providing independent judgment to the Board.

Dr. Chen served as a resident doctor, an attending physician, an associate chief physician and an associate director of general surgery at Shenzhen Second People’s Hospital (The First Affiliated Hospital of Shenzhen University) (深圳市第二人民醫院(深圳大學第一附屬醫院)) from July 1990 to January 1998. He then respectively served as the chief of the medical section and the vice president of Shenzhen Second People’s Hospital from January 1998 to August 2006 and September 2006 to May 2018. Dr. Chen has served as a consultant at Shenzhen Dapeng New Area Medical Health Group (深圳市大鵬新區醫療健康集團) since June 2018.

Dr. Chen obtained a bachelor’s degree in medicine from Wuhan Medical College (武漢醫學院) (currently known as Tongji Medical College of Huazhong University of Science and Technology) in December 1982. He also obtained a master’s degree and a doctorate in medicine from Tongji Medical College of Huazhong University of Science and Technology in July 1987 and June 1990, respectively. In February 2002, he obtained the qualification of chief physician of general surgery from Department of Personnel of Guangdong Province (廣東省人事廳) (currently known as Human Resources and Social Security Department of Guangdong Province (廣東省人力資源和社會保障廳)).

SUPERVISORS

The following table sets forth the key information about the Supervisors.

Name	Age	Position	Responsibilities	Date of appointment as a Supervisor	Date of joining the Group
Sun Jumin (孫聚民)	47	Chairman of the Supervisory Committee	Responsible for overseeing our operations and financial activities	January 10, 2018	January 10, 2018
Liu Fang (劉芳)	45	Supervisor	Responsible for overseeing our operations and financial activities	March 7, 2016	March 7, 2016
Ji Changtao (紀昌濤)	34	Supervisor	Responsible for overseeing our operations and financial activities	May 20, 2021	May 20, 2021

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Name	Age	Position	Responsibilities	Date of appointment as a Supervisor	Date of joining the Group
Dr. Yi Jizu	60	Supervisor	Responsible for overseeing our operations and financial activities as well as leading the quality center	May 25, 2021	April 11, 2016
Zhang Jing (張敬)	40	Supervisor	Responsible for overseeing our operations and financial activities as well as leading the R&D center	February 26, 2018	January 17, 2011

The PRC Company Law requires a joint stock company with limited liability to establish a supervisory committee. The Supervisory Committee currently consists of five members.

Sun Jumin (孫聚民), aged 47, has served as a Supervisor and the chairman of the Supervisory Committee since January 2018. He is responsible for overseeing our operations and financial activities.

Mr. Sun served in various management positions at the finance department and the strategic investment department of CSPC (a company listed on the Stock Exchange (stock code: 1093)) from April 2004 to November 2012, with his last position as the senior director at the finance department. He then was transferred to the headquarters of CSPC Group where he served as the senior director at finance department from November 2012 to August 2015. Mr. Sun respectively served as the president assistant at the headquarters of CSPC Group from March 2014 to August 2015, and the senior director at comprehensive operation department of CSPC from March 2014 to October 2016. He then has served as the vice president at the headquarters of CSPC Group since October 2016. Mr. Sun also successively served as the senior director at finance department of CSPC from July 2017 to August 2018, and the general manager at finance center of CSPC from August 2018 to December 2020. He has served as the deputy general manager at the capital operation center of CSPC Group since November 2020.

Mr. Sun obtained a bachelor’s degree in business administration in July 1997 from Zhongnan University of Finance and Economics (中南財經大學) (currently known as Zhongnan University of Economics and Law (中南財經政法大學)) in the PRC and a master’s degree in senior management business administration from Tsinghua University in January 2015. He also respectively received the qualification of senior accountant issued by the Title Reform Leading Group Office of Hebei Province (河北省職稱改革領導小組辦公室) in January 2000, and the certificate of membership issued by the Chinese Institute of Certified Public Accountants (中國註冊會計師協會) in July 2010.

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Liu Fang (劉芳), aged 45, has served as a Supervisor since March 2016. She is responsible for overseeing our operations and financial activities.

Ms. Liu served as the finance officer of Wuhan YZY Automobile Service Co., Ltd. (武漢友芝友汽車服務有限公司) (a company controlled by Yuan Qian and primarily engaged in new car retail business, which does not compete and is unlikely to compete, directly or indirectly, with the Company’s business) from March 2006 to March 2010 and a finance manager of Wuhan Qianhe Diandang Co., Ltd. (武漢謙和典當有限公司) from April 2010 to December 2011. Since January 2012, Ms. Liu has served as a finance manager of YZY Industrial Group Co., Ltd. (友芝友實業集團有限公司).

Ms. Liu obtained an associate’s degree in modern accounting from the Hubei University of Economic and Management (湖北經濟管理大學) in the PRC in June 1999. She was recognized as a junior accountant 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) and the Ministry of Finance of the PRC (中華人民共和國財政部) in May 2009.

Ji Changtao (紀昌濤), aged 34, has served as a Supervisor since May 2021. He is responsible for overseeing our operations and financial activities.

Mr. Ji served as a key customer representative at Shenzhen Sanofi Pasteur Biological Products Co., Ltd. (深圳賽諾菲巴斯德生物製品有限公司) from April 2014 to June 2015. He then served as an investment manager of the investment and development department of Shenzhen ASB Ventures Holdings Co., Ltd (深圳澳銀資本管理有限公司) from June 2015 to September 2016. Mr. Ji has served as an investment director and a supervisor of BGI Co-Win (Shenzhen) Private Equity Co., Ltd. (華大共贏(深圳)股權投資基金管理有限公司) since September 2016 and March 2020, respectively. He has also served as an investment partner at investment department of BioSpiritus (Shenzhen) Private Equity Fund Management Partnership (Limited Partnership) (柏穗(深圳)私募股權基金管理合夥企業(有限合夥)) since April 2020, and a director of Meitek Technology (Qingdao) Co., Ltd. (美泰科技(青島)股份有限公司) since January 2022.

Mr. Ji obtained a bachelor’s degree in biotechnology in June 2011 from Huazhong University of Science and Technology (華中科技大學) in the PRC and a master’s degree in bioengineering from South China Sea Institute of Oceanology, Chinese Academy of Sciences (中國科學院南海海洋研究所) in the PRC in July 2014.

Dr. Yi Jizu, aged 60, has served as a Supervisor since May 2021. He is responsible for overseeing our operations and financial activities as well as leading the quality center. He joined the Group as a vice president of quality in charge of the Group’s quality center in April 2016 and has served as the senior vice president of quality since December 2019.

Dr. Yi began to work as a research professor in the department of pathology at Mount Sinai School of Medicine in the U.S. in July 2000. He served as a chief scientist at Becton, Dickinson and Company (a company listed on the New York Stock Exchange (stock symbol:

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BDX)) from September 2003 to May 2014. He also worked in WuXi Biologics Co., Ltd. (無錫藥明生物技術股份有限公司), which is a subsidiary of Wuxi Biologics (Cayman) Inc. (藥明生物技術有限公司) (a company listed on the Stock Exchange (stock code: 2269)) from June 2014 to April 2016. He has served as an off-campus supervisor for graduate students at the College of Life Science and Technology of Huazhong University of Science and Technology (華中科技大學生命科學與技術學院) in the PRC since September 2020. He has also served as a professional reviewer of the journal *Frontiers in Pharmacology* since March 2022.

Dr. Yi obtained a bachelor’s degree in analytical chemistry in July 1982 and a master’s degree in physical chemistry in December 1985 from Central South University (中南大學), respectively. He obtained a doctorate in biochemistry from Rutgers the State University in the U.S. in October 1997.

Dr. Yi was named as one of the Wuhan High-Tech Development “3551” Talents (武漢高新技術開發“3551”人才) by the Regulatory Commission of Wuhan East Lake High-Tech Development Zone (武漢東湖高新技術開發區管理委員會) in December 2018. He was honored with a lifetime honorary member of the Chinese Antibody Society (華人抗體協會). Dr. Yi obtained the qualification of senior engineer approved by Office of the Leading Group for Title Reform in Hubei Province (湖北省職稱改革工作領導小組辦公室) in April 2020. He was also named a High-End Expert in the Authoritative Think Tank (權威專家庫高端專家) by the Department of Science and Technology of Hubei Province (湖北省科學技術廳) in March 2022.

Zhang Jing (張敬), aged 40, has served as a Supervisor since February 2018. Mr. Zhang joined the Group in January 2011 and successively served as a senior research assistant in the R&D center of the Company, a senior manager of the cell line development department of the Company and a director of the R&D center of the Company. In May 2023, he was promoted as the senior director of the R&D center of the Company. He is responsible for overseeing our operations and financial activities as well as leading the R&D center.

Prior to joining the Group, Mr. Zhang served as a research assistant at the Institute of Biophysics of the Chinese Academy of Science (中國科學院生物物理研究所) from August 2008 to December 2010. Mr. Zhang has also served as a supervisor of Wuhan Huiyou Juyou Enterprise Management Co., Ltd. (武漢匯友聚友企業管理有限公司) since June 2022.

Mr. Zhang obtained a bachelor’s degree in biotechnology from Wuhan University (武漢大學) in June 2004. He then obtained a master’s degree in biochemistry and molecular biology from the Graduate School of the Chinese Academy of Science (中國科學院研究生院) (currently known as the University of Chinese Academy of Science (中國科學院大學)), in July 2008. He was recognized as an intermediate biochemical engineer by the Wuhan Professional Title Reform Leading Group (武漢市職稱改革工作領導小組) in November 2011.

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SENIOR MANAGEMENT

The following table sets forth the key information about the senior management of the Company.

Name	Age	Position	Responsibilities	Date of appointment as senior management	Date of joining the Group
Dr. Zhou Pengfei	56	Co-founder of the Group, chairman of the Board, executive Director, and chief executive officer	Responsible for the overall strategic planning of the Group	July 8, 2010	July 8, 2010
Dr. Yi Jizu	60	Senior vice president of quality	Responsible for the Group’s quality control	April 11, 2016	April 11, 2016
Dr. Yang Bin (楊彬)	41	Vice president of the manufacturing center	Responsible for implementing the Group’s strategies and goals for technology development and product manufacturing	June 3, 2021	June 3, 2021
Zhang Jing (張敬)	40	Senior director of the R&D center	Responsible for managing projects and research in relation to bispecific antibody drug development	January 17, 2011	January 17, 2011
Dr. Huang Shaoyi (黃劭毅)	43	Senior director of the clinical department	Responsible for academic support of the Group’s clinical projects and developing policies and management processes related to our clinical research	July 13, 2020	July 13, 2020

For the biographical details of Dr. Zhou Pengfei, please refer to the paragraphs headed “– Directors” in this section. For the biographical details of Dr. Yi Jizu and Zhang Jing, please refer to the paragraphs headed “– Supervisors” in this section.

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Dr. Yang Bin (楊彬), aged 41, has served as the vice president of the manufacturing center of the Company since June 2021. He is responsible for implementing the Group’s strategies and goals for technology development and product manufacturing.

Dr. Yang has over ten years of experience in CMC processes management and drug development. He served in various positions pertaining to research and development of biopharmaceuticals at Shenzhen HEC Industrial Development Co., Ltd. (深圳市東陽光實業發展有限公司) and its subsidiaries (“**HEC Group**”). From July 2008 to May 2021, he successively served as an R&D engineer, the head of the monoclonal antibody department, the deputy director and a project manager at the biopharmaceuticals research institute of the HEC Group.

Dr. Yang obtained a bachelor’s degree in pharmacy in June 2003 from Wuhan University (武漢大學) and a master’s degree in microbiology and biochemical pharmacy from Shenyang Pharmaceutical University (沈陽藥科大學) in the PRC in July 2008. In June 2020, he obtained a doctorate in biology (biomedicine) from Jinan University (暨南大學) in the PRC.

Dr. Huang Shaoyi (黃劭毅), aged 43, joined our Group and served as the director of the clinical department of the Company in July 2020. In May 2023, he was promoted as the senior director of the clinical department of the Company. He is responsible for academic support of the Group’s clinical projects and developing policies and management processes related to our clinical research.

Dr. Huang has extensive experience in clinical research and product development. He served as the deputy director of the medical oncology department of Wuhan YZY Medical Science and Technology Co., Ltd. (武漢友芝友醫療科技股份有限公司) from March 2014 to July 2020, where he was responsible for R&D and clinical work.

Dr. Huang obtained a bachelor’s degree in biotechnology in June 2001 and a master’s degree in microbiology in December 2004 from Wuhan University (武漢大學), respectively. After completion of about ten years of doctoral studies, Dr. Huang obtained a doctorate in cancer biology from the University of Texas Health Science Center at Houston and the University of Texas M.D. Anderson Cancer Center in the U.S. in August 2013.

As of the Latest Practicable Date, to the best of the knowledge, information and belief of the Directors after having made all reasonable enquiries,

- (i) save as disclosed above, none of the Directors, Supervisors or senior management has held any directorship in any public company the securities of which are listed on any securities market in Hong Kong or overseas during the three years immediately preceding the date of this document;
- (ii) none of the Directors or Supervisors had any interests in any business, 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;

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- (iii) none of the Directors, Supervisors or members of the senior management of the Company was related to any other Directors, Supervisors and members of the senior management;
- (iv) save as disclosed in “Appendix VI – Statutory and General Information,” none of the Directors, Supervisors or chief executive officer of the Company held any interest in the Shares which would be required to be disclosed pursuant to Part XV of the Securities and Futures Ordinance; and
- (v) there was no additional matter with respect to the appointment of the Directors or Supervisors that needs to be brought to the attention of the Shareholders, and there was no additional information relating to the Directors or Supervisors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules.

JOINT COMPANY SECRETARIES

Zheng Jianhua (鄭建華) joined the Group in August 2021 and was appointed as one of our joint company secretaries in November 2022. Mr. Zheng currently serves as the senior manager at our strategic development department, responsible for corporate financing and legal affairs. He has nearly 20 years of experience in legal practice and has a combined knowledge background of law, finance and securities. Prior to joining the Group, he served as a law teacher in Xiangfan College (襄樊學院) till March 2011, and as a part-time lawyer of Hubei Dongsheng Law Firm (湖北東升律師事務所). From April 2011 to January 2015, Mr. Zheng served as a manager of legal compliance department of Shaanxi Branch of China Life Property and Casualty Insurance Co., Ltd. (中國人壽財產保險股份有限公司陝西省分公司). He also worked in Zhongying Fund Management Co., Ltd. (中盈基金管理有限公司). From January 2016 to August 2021, he served as a legal manager of Wuhan Yitong Culture and Education Co., Ltd. (武漢億童文教股份有限公司).

Mr. Zheng obtained a bachelor’s degree in literature from Zhejiang University (浙江大學) in the PRC in June 2001 and a master’s degree in law from Northwest College of Political Science and Law (西北政法學院) (currently known as Northwest University of Political Science and Law (西北政法大學)) in the PRC in July 2004. He also obtained the legal professional qualification certificate in the PRC (中國法律職業資格證書) issued by the Ministry of Justice of the PRC (中華人民共和國司法部) in September 2002, the Lawyer’s Practising Certificate (律師執業證書) issued by the Department of Justice of Hubei Province (湖北省司法廳) in November 2008, the qualification of Certified Public Valuer (資產評估師證書) issued by China Appraisal Society (中國資產評估協會) in September 2019 and the certificate for passing all the required subjects of the National Uniform CPA Examination issued by the Certified Public Accountant Examination Committee of the Ministry of Finance of PRC (中華人民共和國財政部註冊會計師考試委員會) in December 2019.

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Lai Janette Tin Yun (賴天恩) was appointed as one of our joint company secretaries on [●], with her appointment taking effect on the [REDACTED]. Ms. Lai is a senior manager of the corporate services of Tricor Services Limited, a global professional services firm. She has over ten years of experience providing professional corporate services to Hong Kong listed companies as well as multinational, private and offshore companies.

Ms. Lai obtained a bachelor’s degree in accounting from Hong Kong Shue Yan University (香港樹仁大學) in July 2011. She is a chartered secretary, a chartered governance professional, and a member of both The Hong Kong Chartered Governance Institute (HKCGI) (formerly known as The Hong Kong Institute of Chartered Secretaries (HKICS)) and The Chartered Governance Institute (CGI) (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom.

BOARD COMMITTEES

We have established three Board Committees in accordance with the relevant PRC laws and regulations, the Articles of Association and the Corporate Governance Code, namely the Audit Committee, the Nomination Committee and the Remuneration Committee.

Audit Committee

We have established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of the Corporate Governance Code. The Audit Committee consists of three Directors, namely Fu Lili (付黎黎), Dr. Zhou Hongfeng (周宏峰) and Dr. Deng Yuezhen (鄧躍臻), with Ms. Fu currently serving as the chairwoman. Ms. Fu has the appropriate professional experiences as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the Audit Committee include, but are not limited to, the following:

- (i) proposing the appointment or change of external auditors to our Board, monitoring the independence of external auditors and evaluating their performance;
- (ii) examining the financial information of the Company and reviewing financial reports and statements of the Company;
- (iii) examining the financial reporting system, the risk management and internal control system of the Company, overseeing their rationality, efficiency and implementation and making recommendations to our Board; and
- (iv) dealing with other matters that are authorized by the Board.

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Nomination Committee

We have established a Nomination Committee with written terms of reference in compliance with Rule 3.27A of the Listing Rules and paragraph B.3 of the Corporate Governance Code. The Nomination Committee consists of three Directors, namely Dr. Zhou Pengfei, Dr. Cheng Bin (程斌) and Dr. Dai Weiguo, with Dr. Zhou currently serving as the chairman. The primary duties of the Nomination Committee include, but are not limited to, the following:

- (i) conducting extensive search and providing our Board with suitable candidates for our Directors, general managers and other members of the senior management;
- (ii) reviewing the structure, size and composition of our Board (including but not limited to, gender, age, cultural and educational background, ethnicity, skills, knowledge and experience) at least annually and make recommendations on any proposed changes to the Board to complement the Company’s corporate strategy;
- (iii) researching and developing standards and procedures for the election of our Board members, general managers and members of the senior management, and making recommendations to our Board;
- (iv) assessing the independence of the independent non-executive Directors; and
- (v) dealing with other matters that are authorized by the Board.

Remuneration Committee

We have established a Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of the Corporate Governance Code. The Remuneration Committee consists of three Directors, namely Dr. Cheng Bin (程斌), Dr. Chen Bin (陳斌) and Yuan Qian (袁謙), with Dr. Cheng currently serving as the chairman. The primary duties of the Remuneration Committee include, but are not limited to, the following:

- (i) advising our Board on the overall remuneration plan and structure of our Directors and senior management and the establishment of transparent and formal procedures for determining the remuneration policy of the Company;
- (ii) monitoring the implementation of the remuneration system of the Company;
- (iii) making recommendations on the remuneration packages of our Directors and senior management; and
- (iv) other duties conferred by our Board.

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KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract, (ii) a confidentiality agreement and (iii) a non-competition agreement with our senior management members and other key personnel. Set forth below are the key terms of these contracts we normally enter into with our senior management and other key personnel.

Confidentiality

The employee shall, during the course of employment with the Group and thereafter, keep in confidence all confidential information (including but not limited to trade secrets, technical secrets and management secrets) that belongs to the Group. During the term of employment, the employee shall not, without clear written authorization from the Company, directly or indirectly, disclose or divulge any confidential information of the Group to any third party in any way and shall not use such confidential information apart from discharging his/her duties as an employee of the Group. The employee is also obliged to prevent the disclosure, leakage, loss of and improper use of confidential information in relation to the Group. The employee shall return the documents and materials of the Group upon the termination of his/her employment contract. Such obligations of confidentiality shall subsist for the term of his/her employment and after the termination of his/her employment contract so long as the confidential information is not known to the public.

Non-competition

The non-competition obligations shall subsist throughout the employee's period of employment and up to two years after termination of employment. During the non-competition period, the employee shall not seek, induce, cause, allow, or assist other employees of the Company to terminate his or her labor relations or employment relationship with the Company, nor shall they act as an intermediary or contact person to support or assist any other employee to terminate his or her labor relations or employment relationship with the Company. During the term of employment, the employee shall not work, hold any position, or serve as a consultant in any other company, unit, or economic entity and shall remain in compliance with his or her social and legal obligations in accordance with the applicable laws. The employee shall not engage in any business or engage in a course of employment that produces, or operates products, or provides services that are the same or similar to those offered by the Company, including acting as a partner, director, supervisor, manager, working staff, agent, advisor or any other collaborations. Regardless of the reason for the employee's departure, the employee shall provide us with a written notification pertaining to the name, nature and main business of the new employer before taking up employment with the new employer.

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Intellectual Property Rights

The Company has a complete, absolute and exclusive right, title and interest in the work (including but not limited to the invention, utility model, design and technical solution) that the employee produces, solely or jointly with others, during the period of the employee’s employment with the Company that relates to the Company’s business.

CORPORATE GOVERNANCE CODE

The Company is committed to achieving a high standard of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, the Company intends to comply with the Corporate Governance Code set out in Appendix 14 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules after the [REDACTED].

Pursuant to code provision C.2.1 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between the chairperson and the chief executive officer should be segregated and should not be performed by the same individual. We do not have a separate chairperson and chief executive officer and Dr. Zhou Pengfei currently performs these two roles. The Board believes that vesting the roles of both the chairperson and chief executive officer in the same person has the benefit of ensuring consistent leadership within the Group and enables more effective and efficient overall strategic planning for the Group. The Board considers that the balance of power and authority for the present arrangement will not be impaired and this structure will enable the Company to make and implement decisions promptly and effectively. The Board will continue to review and consider splitting the roles of the chairperson of the Board and the chief executive officer of the Company if and when it is appropriate taking into account the circumstances of the Group as a whole.

Save as disclosed above, the Company intends to comply with all code provisions under the Corporate Governance Code after the [REDACTED].

BOARD DIVERSITY POLICY

We have adopted the board diversity policy which sets out the objective and approach for achieving and maintaining the diversity of the Board in order to enhance its effectiveness. In accordance with the board diversity policy, the Company seeks to achieve board diversity by taking into account a number of factors, including but not limited to gender, age, cultural and educational background, professional experience, skills, knowledge and/or length of service. The ultimate selection of Board candidates will be based on merit and potential contribution to our Board having due regard to the benefits of diversity on the Board and also the specific needs of the Company without focusing on a single diversity aspect. Our Directors have a balanced mix of knowledge and skills, including overall management and strategic development as well as knowledge and experience in areas such as biology, medicine and finance. They obtained degrees in various areas including molecular immunology, clinical

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

medicine, bioscience and economics. Furthermore, our Board has a diverse age and gender representation. Our Board currently comprises two female Directors and 12 male Directors, ranging from 37 years old to 60 years old.

With regards to gender diversity on the Board, we recognize the particular importance of gender diversity. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of the Company, including but without limitation at our Board and senior management levels. We will maintain a focus on gender diversity when recruiting staff at the mid to senior level so as to develop a pipeline of potential female successors to our Board. The Group will also identify and select several female individuals with a diverse range of skills, experience and knowledge in different fields from time to time, and maintain a list of such female individuals who possess qualities to become our Board members, which will be reviewed by our nomination committee periodically to maintain gender diversity of our Board. Taking into account our existing business model and specific needs as well as the different background of our Directors, the composition of our Board satisfies our board diversity policy.

Upon the [REDACTED], the Nomination Committee will from time to time discuss and agree on expected goals to ensure board diversity, and review and, where necessary, update the board diversity policy to ensure that the policy remains effective. The Company will disclose the biographical details of each Director and report on the implementation of the board diversity policy (including whether we have achieved board diversity) in its annual corporate governance report.

DIRECTORS’, SUPERVISORS’ AND CHIEF EXECUTIVE OFFICER’S REMUNERATION AND REMUNERATION OF THE FIVE HIGHEST-PAID INDIVIDUALS

The Directors, Supervisors and senior management members who receive remuneration from the Company are paid in the forms of salaries and other benefits in kind, discretionary bonuses, retirement benefit scheme contributions and share-based payment. The remuneration of the Directors, Supervisors and senior management members is determined with reference to the remuneration paid by comparable companies and the achievement of major operating indicators of the Company.

The aggregate amount of remuneration (including salaries and other benefits in kind, discretionary bonuses, retirement benefit scheme contributions and share-based payment) and other benefits in kind paid to the Directors, Supervisors and the chief executive officer of the Company for the years ended December 31, 2021 and 2022 amounted to RMB20.9 million and RMB4.9 million, respectively. The aggregate amount of remuneration (including salaries and other benefits in kind, discretionary bonuses, retirement benefit scheme contributions and share-based payment) and other benefits in kind incurred by the five highest-paid individuals (including one Director and two Supervisors of the Company) of the Group for the years ended December 31, 2021 and 2022 amounted to RMB25.3 million (including share-based payments of RMB19.6 million) and RMB7.3 million (including share-based payments of RMB0.4 million), respectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Our Company offers executive Director and senior management members, who are our employees, compensation in the form of salaries and other benefits, discretionary bonus, retirement benefit scheme contributions and share-based payments. The independent non-executive Directors receive compensation based on their responsibilities.

Under the current compensation arrangement, we estimate the total compensation before taxation, including estimated share-based compensation, to be accrued to our Directors, Supervisors and the chief executive officer of the Company for the year ending December 31, 2023 to be approximately RMB4.7 million. The actual remuneration of Directors and Supervisors for 2023 may be different from the expected remuneration.

We confirmed that during the Track Record Period, no remuneration was paid by the Company to, or receivable by, our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining the Company or as compensation for loss of office in connection with the management positions of the Company or any subsidiary of the Company.

During the Track Record Period, none of our Directors or Supervisors waived any remuneration. Save as disclosed above, no other payments have been paid, or are payable, by the Company or our subsidiary to our Directors, Supervisors or the five highest-paid individuals during the Track Record Period.

COMPLIANCE ADVISER

The Company has appointed Gram Capital Limited as our Compliance Adviser in compliance with Rules 3A.19 and 19A.05 of the Listing Rules. The Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and other applicable laws, rules, codes and guidelines. Pursuant to Rule 3A.23 of the Listing Rules, the Compliance Adviser will advise the Company in certain circumstances including:

- (i) before the publication of any regulatory announcement, circular or financial report;
- (ii) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- (iii) where we propose 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
- (iv) where the Stock Exchange makes an inquiry to the Company in accordance with Rule 13.10 of the Listing Rules.

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Pursuant to Rule 19A.06 of the Listing Rules, the Compliance Adviser will, on a timely basis, inform the Company of any amendment or supplement to the Listing Rules that are announced by the Stock Exchange. The Compliance Adviser will also inform the Company of any new or amended law, regulation or code in Hong Kong applicable to us, and advise us on the continuing requirements under the Listing Rules and applicable laws and regulations.

The term of the appointment will commence on the [REDACTED] and is expected to end on the date on which the Company complies with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

SHARE CAPITAL

IMMEDIATELY BEFORE THE COMPLETION OF THE [REDACTED]

As of the Latest Practicable Date, the issued share capital of the Company was RMB182,000,000, comprising 167,213,746 Domestic Shares and 14,786,254 [REDACTED] Foreign Shares with a nominal value of RMB1.00 each.

UPON THE COMPLETION OF THE [REDACTED]

Immediately following the completion of the [REDACTED] and the conversion of the [REDACTED] Shares into H Shares, assuming the [REDACTED] is not exercised, the share capital of the Company will be as follows:

Description of Shares ⁽²⁾	Number of Shares	Approximate percentage to the total share capital of the Company (%)
Domestic Shares in issue	[REDACTED]	[REDACTED]
[REDACTED] Foreign Shares in issue	[REDACTED]	[REDACTED]
H Shares converted from Domestic Shares ⁽¹⁾	[REDACTED]	[REDACTED]
H Shares converted from [REDACTED] Foreign Shares ⁽¹⁾	[REDACTED]	[REDACTED]
H Shares issued under the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]

(1) Please refer to the paragraphs headed “History, Development and Corporate Structure – [REDACTED] Investments – Capitalization of the Company” in this document for details of the identities of the Shareholders whose Shares will be converted into H Shares upon [REDACTED].

(2) For the avoidance of doubt, both [REDACTED] Shares (comprising Domestic Shares and [REDACTED] Foreign Shares) and H Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares.

SHARE CAPITAL

Immediately following the completion of the [REDACTED] and the conversion of the [REDACTED] Shares into H Shares, assuming the [REDACTED] is fully exercised, the share capital of the Company will be as follows:

Description of Shares ⁽²⁾	Number of Shares	Approximate percentage to the total share capital of the Company (%)
Domestic Shares in issue	[REDACTED]	[REDACTED]
[REDACTED] Foreign Shares in issue	[REDACTED]	[REDACTED]
H Shares converted from Domestic Shares ⁽¹⁾	[REDACTED]	[REDACTED]
H Shares converted from [REDACTED] Foreign Shares ⁽¹⁾	[REDACTED]	[REDACTED]
H Shares issued under the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]

(1) Please refer to the section headed “History, Development and Corporate Structure – [REDACTED] Investments – Capitalization of the Company” in this document for details of the identities of the Shareholders whose Shares will be converted into H Shares upon [REDACTED].

(2) For the avoidance of doubt, both [REDACTED] Shares (comprising Domestic Shares and [REDACTED] Foreign Shares) and H Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares.

PUBLIC FLOAT REQUIREMENTS

Rules 8.08(1)(a) and (b) of the Listing Rules require there to be an open market in the securities for which [REDACTED] is sought and for a sufficient public float of an issuer’s [REDACTED] securities to 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 the public; and (ii) where an issuer has one class of securities or more apart from the class of securities for which [REDACTED] is sought, the total securities of the issuer held by the public (on all regulated market(s) including the Stock Exchange) at the time of [REDACTED] must be at least 25% of the issuer’s total issued share capital.

Based on the information in the above tables, the Company will meet the public float requirement under the Listing Rules after the completion of the [REDACTED] (whether the [REDACTED] is fully exercised or not).

SHARE CAPITAL

OUR SHARES

The H Shares, to be issued following the completion of the [REDACTED] and converted from the [REDACTED] Shares, and the [REDACTED] Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares. Apart from certain qualified domestic institutional investors in the PRC, qualified PRC investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and other persons entitled to hold H Shares pursuant to the relevant PRC laws and regulations or upon approval by any competent authorities, H Shares generally may not be subscribed for by, or traded between, investors of the PRC. H Shares may only be subscribed for and traded in Hong Kong dollars.

[REDACTED] Shares and H Shares are regarded as one class of Shares under our Articles of Association and will rank pari passu with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this document. Dividends in respect of our Shares may be paid by us in Hong Kong dollars or Renminbi, as the case may be. In addition to cash, dividends may be distributed in the form of Shares.

CONVERSION OF [REDACTED] SHARES INTO H SHARES

[REDACTED]

SHARE CAPITAL

[REDACTED]

DOMESTIC PROCEDURES

The Full Circulation Participating Shareholders may only deal in the Shares upon completion of the below arrangement procedures for the registration, deposit and transaction settlement in relation to the conversion and [REDACTED]:

- (i) We will appoint CSDC as the nominal holder to deposit the relevant securities at CSDC (Hong Kong), which will then deposit the securities at HKSCC in its own name. CSDC, as the nominal holder of the Full Circulation Participating Shareholders, shall handle all custody, maintenance of detailed records, crossborder settlement and corporate actions, etc. relating to the converted H Shares for the Full Circulation Participating Shareholders;
- (ii) We will engage a domestic securities company (the “Domestic Securities Company”) to provide services such as the transmission of sale orders and trading messages in respect of the converted H Shares. The Domestic Securities Company will engage a Hong Kong securities company (the “Hong Kong Securities Company”) for settlement of share transactions. We will make an application to CSDC, Shenzhen Branch for the maintenance of a detailed record of the initial holding of the converted H Shares held by our Shareholders. Meanwhile, we will submit applications for a domestic transaction commission code and abbreviation, which shall be confirmed by CSDC, Shenzhen Branch as authorized by Shenzhen Stock Exchange (“SZSE”);

SHARE CAPITAL

- (iii) The SZSE shall authorize Shenzhen Securities Communication Co., Ltd. to provide services relating to transmission of trading orders and trading messages in respect of the Converted H Shares between the Domestic Securities Company and the Hong Kong Securities Company, and the real-time market forwarding services of the H Shares;
- (iv) According to the Notice of the SAFE on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》), the Full Circulation Participating Shareholders that held Domestic Shares shall complete the overseas shareholding registration with the local foreign exchange administration bureau before the Shares are sold, and after the overseas shareholding registration, open a specified bank account for the holding of overseas shares by domestic investors at a domestic bank with relevant qualifications and open a fund account for the H Share “Full Circulation” at the Domestic Securities Company. The Domestic Securities Company shall open a securities trading account for the H Share “Full Circulation” at the Hong Kong Securities Company; and
- (v) The Full Circulation Participating Shareholders shall submit trading orders of the Converted H Shares through the Domestic Securities Company. Trading orders of the Full Circulation Participating Shareholders for the relevant Shares will be submitted to the Stock Exchange through the securities trading account opened by the Domestic Securities Company at the Hong Kong Securities Company. Upon completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDC, CSDC and the Domestic Securities Company, and the Domestic Securities Company and the Full Circulation Participating Shareholders, will all be conducted separately.

As a result of the conversion, the shareholding of the relevant Full Circulation Participating Shareholders in our share capital registered shall be reduced by the number of Domestic Shares and [REDACTED] Foreign Shares converted and increased by the number of H Shares so converted.

A Shareholder holding Domestic Shares not converted into H Shares can work with the Company according to the Articles of Association and follow the procedures set out in this document to convert the Domestic Shares into H Shares after the [REDACTED] if they want, provided that such conversion of Domestic Shares into and [REDACTED] and [REDACTED] of H Shares will be subject to the approval of the relevant PRC regulatory authorities, including the CSRC, the approval of the Stock Exchange and the satisfaction of the public float requirement under the Listing Rules by the Company.

SHARE CAPITAL

RESTRICTIONS OF SHARE TRANSFER

In accordance with the PRC Company Law, the shares issued prior to any public offering of shares by a company cannot be transferred within one year from the date on which such publicly offered shares are [REDACTED] and [REDACTED] on the relevant stock exchange. As such, the Shares issued by the Company prior to the issue of H Shares will be subject to such statutory restriction on transfer within a period of one year from the [REDACTED].

Our Directors, Supervisors and members of the senior management of the Company shall declare their shareholdings in the Company and any changes in their shareholdings. Shares transferred by our Directors, Supervisors and members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in the Company. The Shares that the aforementioned persons held in the Company cannot be transferred within one year from the date on which the Shares are [REDACTED] and traded, nor within half a year after they leave their positions in the Company. The Articles of Association may contain other restrictions on the transfer of the Shares held by our Directors, Supervisors and members of senior management of the Company.

REGISTRATION OF SHARES NOT [REDACTED] ON AN OVERSEAS STOCK EXCHANGE

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (《關於境外上市公司非境外上市股份集中登記存管有關事宜的通知》) issued by the CSRC, the Company is required to register and deposit our Shares that are not [REDACTED] on the overseas stock exchange with the CSDC within 15 business days after the [REDACTED] and provide a written report to the CSRC regarding the centralized registration and deposit of our Shares that are not [REDACTED] on the overseas stock exchange as well as the [REDACTED] and [REDACTED] of our H Shares.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the conversion of the [REDACTED] Shares to H Shares and assuming the [REDACTED] is not exercised, the following persons will have an interest and/or short position in the Shares or the underlying Shares which would fall 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 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 the Company:

Name of Shareholder	Capacity/Nature of interest	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)		
		Number and description of the Shares ⁽⁹⁾	Approximate percentage of interest in the Company	Number and description of the Shares ⁽⁹⁾	Approximate percentage of interest in the Company ⁽¹⁾	Approximate percentage of interest in the [REDACTED] Shares/H Shares (as appropriate) ⁽¹⁾⁽⁹⁾
Yuan Qian ⁽²⁾	Beneficial owner; interest held jointly with other persons	47,392,561 Domestic Shares	26.04%	[REDACTED] Shares	[REDACTED]	[REDACTED]
		6,869,744 [REDACTED]	3.77%			([REDACTED] Shares)
		Foreign Shares				
Dr. Zhou Pengfei ⁽²⁾	Beneficial owner; interest held jointly with other persons	47,392,561 Domestic Shares	26.04%	[REDACTED] Shares	[REDACTED]	[REDACTED]
		6,869,744 [REDACTED]	3.77%			([REDACTED] Shares)
		Foreign Shares				
Dr. Zhou Hongfeng ⁽²⁾	Beneficial owner; interest held jointly with other persons	47,392,561 Domestic Shares	26.04%	[REDACTED] Shares	[REDACTED]	[REDACTED]
		6,869,744 [REDACTED]	3.77%			([REDACTED] Shares)
		Foreign Shares				
Wuhan Caizhi ⁽²⁾	Beneficial owner; interest held jointly with other persons	47,392,561 Domestic Shares	26.04%	[REDACTED] Shares	[REDACTED]	[REDACTED]
		6,869,744 [REDACTED]	3.77%			([REDACTED] Shares)
		Foreign Shares				
CSPC-NBP ⁽³⁾	Beneficial owner	51,241,785 Domestic Shares	28.15%	[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
CSPC ⁽³⁾	Interest in controlled corporation	51,241,785 Domestic Shares	28.15%	[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Capacity/Nature of interest	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)		
		Number and description of the Shares ⁽⁹⁾	Approximate percentage of interest in the Company	Number and description of the Shares ⁽⁹⁾	Approximate percentage of interest in the Company ⁽¹⁾	Approximate percentage of interest in the [REDACTED] Shares/H Shares (as appropriate) ⁽¹⁾⁽⁹⁾
Dragon Merit Holdings Limited ⁽³⁾	Interest in controlled corporation	51,241,785 Domestic Shares	28.15%	[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
Robust Sun Holdings Limited ⁽³⁾	Interest in controlled corporation	51,241,785 Domestic Shares	28.15%	[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
Caizhi No. 2	Beneficial owner	11,620,411 Domestic Shares	6.38%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
				[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
				[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Tongde Qianyuan ⁽⁴⁾	Interest in controlled corporations	16,882,009 Domestic Shares	9.28%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
				[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
				[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Wen Zhicheng (溫植成) ⁽⁴⁾	Interest in controlled corporations	16,882,009 Domestic Shares	9.28%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
				[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
				[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Huiyou Xingyao ⁽⁴⁾⁽⁵⁾	Beneficial owner	10,142,797 Domestic Shares	5.57%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
				[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
				[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Nanning Yaoyou ⁽⁴⁾⁽⁵⁾	Interest in controlled corporations	10,142,797 Domestic Shares	5.57%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
				[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
				[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Dr. Guo Hongwei (郭宏偉) ⁽⁵⁾	Interest in controlled corporations	10,142,797 Domestic Shares	5.57%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
				[REDACTED] H Shares	[REDACTED]	[REDACTED] (H Shares)
				[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Capacity/Nature of interest	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)		Approximate percentage of interest in the [REDACTED] Shares/H Shares (as appropriate) ⁽¹⁾⁽⁹⁾
		Number and description of the Shares ⁽⁹⁾	Approximate percentage of interest in the Company	Number and description of the Shares ⁽⁹⁾	Approximate percentage of interest in the Company ⁽¹⁾	
Wang Jinxu (王金戌) ⁽⁵⁾	Interest in controlled corporations	10,142,797 Domestic Shares	5.57%	[REDACTED] Shares [REDACTED] H Shares	[REDACTED] [REDACTED]	[REDACTED] ([REDACTED] Shares) [REDACTED] (H Shares)
Guanggu New Technology ⁽⁶⁾	Beneficial owner	7,000,000 Domestic Shares	3.85%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Wuhan Hi-Tech ⁽⁶⁾	Interest in controlled corporations	7,000,000 Domestic Shares	3.85%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Guanggu Health ⁽⁷⁾	Beneficial owner	5,600,000 Domestic Shares	3.08%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
Hubei Science & Technology Investment ⁽⁷⁾⁽⁸⁾	Interest in controlled corporations	7,000,000 Domestic Shares	3.85%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)
East Lake Management Committee ⁽⁶⁾⁽⁷⁾⁽⁸⁾	Interest in controlled corporations Interest in controlled corporations	14,000,000 Domestic Shares	7.69%	[REDACTED] Shares	[REDACTED]	[REDACTED] ([REDACTED] Shares)

- (1) The calculation is based on the total number of [REDACTED] Shares and [REDACTED] H Shares in issue upon [REDACTED] comprising (i) an aggregate of [REDACTED] Share to be converted from the [REDACTED] Shares and (ii) [REDACTED] to be issued pursuant to the [REDACTED] (without taking into account the H Shares which may be issued upon the exercise of the [REDACTED]).
- (2) Pursuant to the concert party arrangement dated June 30, 2018 and supplemental concert party agreements dated October 26, 2020 and June 2, 2023 entered into by Yuan Qian, Dr. Zhou Pengfei, Dr. Zhou Hongfeng and Wuhan Caizhi, the AIC Parties agreed (i) to act in concert by way of reaching consensus on proposals related to the Group’s daily management and operation presented to all general meetings and Board meetings of the Company; and (ii) that when no consensus can be reached, the AIC Parties shall vote in concurrence with Yuan Qian on the proposals, or, in the event of Yuan Qian’s absence from voting, the AIC Parties shall vote in concurrence with the AIC Party with the highest shareholding percentage among the AIC Parties who votes at the meetings. As a result, each of the AIC Parties was deemed to be interested in (i) the aggregate of 47,392,561 Domestic Shares held by Yuan Qian, Dr. Zhou Hongfeng and Wuhan Caizhi, and (ii) the 6,869,744 [REDACTED] Foreign Shares held by Dr. Zhou Pengfei.

SUBSTANTIAL SHAREHOLDERS

- (3) *As of the Latest Practicable Date, CSPC-NBP was owned as to 54.06% and 45.94% by CSPC and Dragon Merit Holdings Limited, respectively; and Dragon Merit Holdings Limited was owned as to 100.00% by Robust Sun Holdings Limited, which was wholly owned by CSPC. As a result, each of CSPC, Dragon Merit Holdings Limited and Robust Sun Holdings Limited was deemed to be interested in the 51,241,785 Domestic Shares held by CSPC-NBP under the SFO.*
- (4) *As of the Latest Practicable Date, (i) Nanning Yaoyou was the general partner of Huiyou Xingyao, Tongde Qianyuan was the general partner of Nanning Yaoyou, Tongde Qianyuan was owned as to approximately 72.38% by Wen Zhicheng; (ii) Tongde Tongxin was the general partner of Zhongheng Tongde, Tongde Qianyuan was the general partner of Tongde Tongxin; and (iii) Gongqingcheng Yaoyou was the general partner of Gongqingcheng Huiyou, Tongde Qianyuan was the general partner of Gongqingcheng Yaoyou. As a result, each of Tongde Qianyuan and Wen Zhicheng was deemed to be interested in (i) the 10,142,797 Domestic Shares (among which [REDACTED] Domestic Share will be converted to H Shares upon [REDACTED]) held by Huiyou Xingyao, (ii) the [REDACTED] Domestic Shares (all of which will be converted to H Shares upon [REDACTED]) held by Zhongheng Tongde, and (iii) the [REDACTED] Domestic Shares ([REDACTED] Domestic Shares will be converted to H Shares upon [REDACTED]) held by Gongqingcheng Huiyou under the SFO.*
- (5) *As of the Latest Practicable Date, (i) Nanning Yaoyou was the general partner of Huiyou Xingyao; and (ii) Dr. Guo Hongwei and Wang Jinxu were the limited partners of Nanning Yaoyou with the limited partnership interests of 33.00% and 33.00%, respectively. As a result, each of Nanning Yaoyou, Dr. Guo Hongwei and Wang Jinxu was deemed to be interested in the 10,142,797 Domestic Shares (among which [REDACTED] Domestic Shares will be converted to H Shares upon [REDACTED]) held by Huiyou Xingyao under the SFO.*
- (6) *As of the Latest Practicable Date, Guanggu New Technology was owned as to approximately 98.59% by Wuhan Hi-Tech, which was in turn wholly owned by the state-owned East Lake Management Committee. As a result, each of Wuhan Hi-Tech and East Lake Management Committee was deemed to be interested in the 7,000,000 Domestic Shares held by Guanggu New Technology under the SFO.*
- (7) *As of the Latest Practicable Date, Guanggu Health was wholly owned by Hubei Science & Technology Investment, which was in turn wholly owned by the state-owned East Lake Management Committee. As a result, each of Hubei Science & Technology Investment and East Lake Management Committee was deemed to be interested in the 5,600,000 Domestic Shares held by Guanggu Health under the SFO.*
- (8) *As of the Latest Practicable Date, Guanggu Growth was owned as to approximately 49.09% by Guanggu VC and as to approximately 49.09% by Guanggu Financing Guarantee, respectively. Guanggu VC was owned as to 57.00% by Guanggu Financial Holding Group and as to 43.00% by Wuhan Guanggu Growth Venture Capital Management Co., Ltd. (武漢光谷成長創業投資管理有限公司) (“Guanggu Growth Venture Capital”), respectively. Guanggu Growth Venture Capital was owned as to 35.00% by Guanggu Financial Holding Group. Guanggu Financing Guarantee was owned as to 90.00% by Guanggu Financial Holding Group. Guanggu Financial Holding Group was owned as to approximately 54.61% by Hubei Science & Technology Investment, which was in turn wholly owned by the state-owned East Lake Management Committee. As a result, each of Hubei Science & Technology Investment and East Lake Management Committee was deemed to be interested in the 1,400,000 Domestic Shares held by Guanggu Growth under the SFO.*
- (9) *For the avoidance of doubt, both [REDACTED] Shares and H Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares.*

Save as disclosed above, our Directors are not aware of any person who will, immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), have any interest and/or short position in the Shares or underlying Shares of the Company which will be required to be disclosed to the Company and the Stock Exchange 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 share capital carrying rights to vote in all circumstances at general meeting of the Company or any other member of the Group.

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

In preparation for the [REDACTED], we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemption from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 of the Listing Rules, an issuer must have a sufficient management presence in Hong Kong. This normally means that at least two of its executive directors must be ordinarily resident in Hong Kong. Rule 19A.15 of the Listing Rules further provides that the requirement in Rule 8.12 of the Listing Rules may be waived by having regard to, among other considerations, the new applicant’s arrangements for maintaining regular communication with the Stock Exchange, including but not limited to compliance by the new applicant with Rules 19A.05 to 19A.07 of the Listing Rules.

The Group’s daily operations and major assets are primarily located in the PRC, and the Group’s management members are, and expect to continue to be, based primarily in the PRC. The Company considers that the Group’s management members are best able to attend to its functions by being based in the PRC. The Company’s executive Director is not or will not be ordinarily resident in Hong Kong after the [REDACTED] of the Company. The Directors consider that relocation of the Company’s executive Director to Hong Kong will be burdensome and costly for the Company, and it may not be in the best interests of the Company and its Shareholders as a whole to appoint additional executive Directors who are ordinarily resident in Hong Kong. Furthermore, if the executive Director or the additional ones are not able to be physically present at the location where the Group’s daily operations take place, they may not be able to fully or promptly understand the daily business operation of the Group nor appreciate the circumstances affecting the business operations and development of the Group from time to time.

As such, the Company does not have, and for the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under 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 strict compliance with Rule 8.12 and Rule 19A.15 of the Listing Rules. The Company has made the following arrangements to maintain effective communication between the Stock Exchange and us:

- (i) The Company has appointed and will continue to maintain Dr. Zhou Pengfei and Dr. Zhou Hongfeng (周宏峰) as its authorised representatives (the “**Authorised Representatives**”) pursuant to Rules 3.05 and 19A.07 of the Listing Rules. The Authorised Representatives will act as the Company’s principal communication channel with the Stock Exchange. Each of the Authorised Representatives will be available to meet with the Stock Exchange within a reasonable time frame upon the

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND
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request of the Stock Exchange and will be readily contactable by telephone, facsimile and email. The Company has provided the Stock Exchange with the contact details of the Authorised Representatives and the Company will inform the Stock Exchange promptly in respect of any change to the contact details of the Authorised Representatives;

- (ii) The Authorised Representatives have the means of contacting all Directors (including the independent non-executive Directors) promptly at all times as and when the Stock Exchange proposes to contact a Director with respect to any matter. To enhance communication between the Stock Exchange and the Authorised Representatives or the Directors, the Company will implement a policy whereby (i) the executive Director will provide a valid phone number or other means of communication for the Authorised Representatives when he is traveling or out of office, and (ii) each Director will provide his or her mobile phone number, office phone number, e-mail address and, where available, fax number to the Stock Exchange and the Company will inform the Stock Exchange promptly in respect of any changes to the contact details of the Directors;
- (iii) All the Directors who are not ordinarily resident in Hong Kong have confirmed that they possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with relevant members of the Stock Exchange in Hong Kong upon reasonable notice, when required; and
- (iv) The Company has appointed Gram Capital Limited as the Compliance Adviser upon [REDACTED] pursuant to Rules 3A.19 and 19A.05 of the Listing Rules. The Compliance Adviser will have access at all times to the Authorised Representatives, the Company's Directors and senior management, who will act as the additional channel of communication with the Stock Exchange when the Authorised Representatives are not available. The Company has provided the Stock Exchange with the contact details of the Compliance Adviser and will inform the Stock Exchange promptly in respect of any changes to the contact details of the Compliance Adviser.

The Company will inform the Stock Exchange as soon as practicable in respect of any change in the Authorised Representatives and/or the Compliance Adviser in accordance with the Listing Rules.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND
EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND
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WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary of an issuer must be an individual who, by virtue of his or her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of company secretary. Note 1 to Rule 3.28 of the Listing Rules further provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (i) a member of The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries);
- (ii) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (iii) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

Note 2 to Rule 3.28 of the Listing Rules further sets out the factors that the Stock Exchange will consider in assessing an individual’s “relevant experience”:

- (i) length of employment with the issuer and other issuers and the roles he or she played;
- (ii) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (iii) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (iv) professional qualifications in other jurisdictions.

The Company considers that while it is important for the company secretary to be familiar with the relevant securities regulations in Hong Kong, he/she also needs to have experience relevant to the Company’s operations, a nexus to our Board and a close working relationship with the management of the Company in order to perform the function of a company secretary and to take the necessary actions in the most effective and efficient manner. It is for the benefit of the Company to appoint a person who is familiar with the Company’s business and affairs as company secretary.

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

The Company has appointed Zheng Jianhua (鄭建華) (“**Mr. Zheng**”), as one of the joint company secretaries. Mr. Zheng serves as the senior manager of our strategic development department and is primarily responsible for corporate financing and legal affairs. The Company believes that Mr. Zheng has extensive experience in business management and corporate governance matters, as well as a thorough understanding of the daily operations, internal administration and financial management of the Group accumulated since his joining the Group in August 2021. However, Mr. Zheng currently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules. Therefore, the Company [has appointed] Lai Janette Tin Yun (賴天恩) (“**Ms. Lai**”), a chartered secretary, a chartered governance professional, and a member of both The Hong Kong Chartered Governance Institute (HKCGI) (formerly known as The Hong Kong Institute of Chartered Secretaries (HKICS)) and The Chartered Governance Institute (CGI) (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom, who fully meets the requirements stipulated under Rules 3.28 and 8.17 of the Listing Rules to act as the other joint company secretary and to provide assistance to Mr. Zheng for an initial period of three years from the [REDACTED] to enable Mr. Zheng to acquire the “relevant experience” under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

The following arrangements have been, or will be, put in place to assist Mr. Zheng in acquiring the qualifications and experience required under Rule 3.28 of the Listing Rules:

- (i) Mr. Zheng will endeavor to attend relevant training courses, including briefings on the latest changes to the relevant applicable Hong Kong laws and regulations and the Listing Rules which will be organized by the Company’s Hong Kong legal advisors on an invitation basis and seminars organized by the Stock Exchange for [REDACTED] issuers from time to time;
- (ii) Mr. Zheng has confirmed that he will be attending a total of no less than 15 hours of training courses on the Listing Rules, corporate governance, information disclosure, investors relation as well as the functions and duties of the company secretary of a Hong Kong [REDACTED] issuer during each financial year as required under Rule 3.29 of the Listing Rules;
- (iii) Ms. Lai will assist Mr. Zheng to enable him to acquire the relevant experience (as required under Rule 3.28 of the Listing Rules) to discharge the duties and responsibilities as the company secretary of the Company;

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- (iv) Ms. Lai will communicate regularly with Mr. Zheng on matters relating to corporate governance, the Listing Rules and any other laws and regulations which are relevant to the Company and its affairs. Ms. Lai will work closely with, and provide assistance for, Mr. Zheng in the discharge of his duties as a company secretary, including organizing the Company's Board meetings and Shareholders' general meetings;
- (v) Upon expiry of Mr. Zheng's initial term of appointment as the company secretary of the Company, the Company will evaluate his experience in order to determine if he has acquired the qualifications required under Rule 3.28 of the Listing Rules, and whether on-going assistance should be arranged so that Mr. Zheng's appointment as the company secretary of the Company continues to satisfy the requirements under Rules 3.28 and 8.17 of the Listing Rules. The waiver will be revoked immediately if Ms. Lai ceases to provide assistance to Mr. Zheng as a joint company secretary for the three-year period after the [REDACTED] or where there are material breaches of the Listing Rules by the Company; and
- (vi) The Company has appointed Gram Capital Limited as the Compliance Adviser pursuant to Rules 3A.19 and 19A.05 of the Listing Rules which will act as the additional communication channel with the Stock Exchange (for a period commencing on the [REDACTED] and ending on the date on which the Company complies with Rule 13.46 of the Listing Rules in respect of its financial results for the first full financial year after the date of [REDACTED], or until the engagement is terminated, whichever is earlier). Gram Capital Limited will provide professional guidance and advice to the Company as to the compliance with the Listing Rules and all other applicable laws and regulations.

**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 IN RESPECT OF THE FINANCIAL INFORMATION FOR
THE YEAR ENDED DECEMBER 31, 2020**

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all document to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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

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Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance further requires the company to include in its document a report by the auditors of the company with respect to (i) the profits and losses of the company and (ii) the assets and liabilities of the company for each of the three financial years immediately preceding the issue of the document.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the 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 interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or would otherwise be unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the consolidated results of an issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the [REDACTED] document or such shorter period as may be acceptable to the Stock Exchange be included in the accountants’ report to the document.

Rule 18A.03(3) of the Listing Rules requires that an eligible biotech company must have been in operation in its current line of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules requires that an eligible biotech company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 shall instead reference to “two financial years” or “two years”, as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the [REDACTED] document.

As such, we have applied to the SFC for, and the SFC has [granted], a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the accountants’ report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (i) The Company is a biotechnology company dedicated to developing BsAb-based therapies, and falls within the scope of a biotech company as defined under Chapter 18A of the Listing Rules. The Company is seeking a [REDACTED] under Chapter 18A and will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;

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- (ii) In compliance with the above-mentioned requirements under the Listing Rules, the Accountants’ Report of the Company set out in Appendix I to this document has been prepared to cover the two financial years ended December 31, 2021 and 2022;
- (iii) As of the Latest Practicable Date, the Company had not commercialized any drug candidates or generated any revenue from sales of its drug candidates. Major financing activities conducted by the Company since its incorporation include the [REDACTED] Investments, the details of which have been fully disclosed in the paragraphs headed “History, Development and Corporate Structure – [REDACTED] Investments” in this document;
- (iv) Notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2021 and 2022 in accordance with Chapter 18A of the Listing Rules, 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; and
- (v) The Accountants’ Report covering the two financial years ended December 31, 2021 and 2022 (as set out in Appendix I to this document), together with other disclosures in this document, have already provided adequate and reasonable up-to-date information in the circumstances for the potential investors to make an informed assessment of the business, assets and liabilities, financial position, management and prospects and to form a view on the track record of the Company. Therefore, the exemption would not prejudice the interest of the investing public.

The SFC [has granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting the Company from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance 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 on the condition that particulars of the exemption are set out in this document.

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**WAIVER FROM STRICT COMPLIANCE WITH CLASS MEETING REQUIREMENTS
AND ADDITIONAL REQUIREMENTS REGARDING ARTICLES OF ASSOCIATION
APPLICABLE TO PRC ISSUERS**

**Rules relating to class meeting and other requirements relating to issuance and
repurchase of shares by PRC issuers**

Rule 19A.25(1) of the Listing Rules provides that the share repurchases of a PRC issuer shall be approved by special resolutions of shareholders in general meetings and holders of domestic and foreign shares (and, if applicable, H shares) at meetings of such holders conducted in accordance with the PRC issuer’s articles of association.

Rule 19A.38 of the Listing Rules provides that except in certain circumstances, the directors of a PRC issuer shall obtain the approval by a special resolution of shareholders in general meeting, and the approvals by special resolutions of holders of domestic shares and overseas [REDACTED] foreign shares (and, if applicable, H shares) (each being otherwise entitled to vote at general meetings) at separate class meeting conducted in accordance with the PRC issuer’s articles of association, prior to authorizing, allotting, issuing or granting (i) shares, (ii) securities convertible into shares, or (iii) options, warrants or similar rights to subscribe for shares or such convertible securities.

Paragraphs 56 and 65(a) of Rule 19A.42 of the Listing Rules provide that the content of a [REDACTED] document for the [REDACTED] of equity securities of a PRC issuer no part of whose share capital is already [REDACTED] on the Stock Exchange shall include the quorum and voting for general meetings of shareholders and for separate meetings of holders of domestic shares and foreign shares (and, if applicable, H shares).

**Rules relating to requirements relating to articles of association and [REDACTED]
document**

Rule 19A.45 of the Listing Rules provides that a PRC issuer shall not at any time permit or cause any amendment to its articles of association which would cause the same to cease to comply with the provisions of Appendix 3 or Section 1 of Part D of Appendix 13 to the Listing Rules.

Section 1 of Part D of Appendix 13 to the Listing Rules provides that the articles of association of a PRC issuer whose primary [REDACTED] is or is to be on the Stock Exchange must include the Mandatory Provisions of the Articles of Association for Companies Listing Overseas (the “Mandatory Provisions”) and other ancillary provisions.

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Latest development of New PRC Regulations and its implications

On February 14, 2023, the State Council announced the Decision of the State Council to Repeal Certain Administrative Regulations and Documents (《國務院關於廢止部分行政法規和文件的決定》) and on February 17, 2023, the CSRC announced the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) and five relevant guidelines (collectively, the “**New PRC Regulations**”), which both took effect from March 31, 2023, and repealed the Special Regulations of the State Council on the Overseas Offering and 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》) and the Mandatory Provisions of the Articles of Association for Companies Listing Overseas (《到境外上市公司章程必備條款》) (the “**Mandatory Provisions**”), respectively.

Pursuant to the New PRC Regulations, PRC issuers should formulate their articles of association by reference to the Guidelines for Articles of Association of Listed Companies (《上市公司章程指引》) (the “**Guidelines on Articles**”) issued by CSRC. Given the above and that the Mandatory Provisions have been repealed and are no longer applicable, holders of domestic shares and H shares (which are both ordinary shares of the same class) are no longer deemed as different classes of shareholders. Accordingly, the requirements in relation to (i) class meetings for holders of domestic shares and H shares and relevant disclosure requirements in the [REDACTED] documents under Rules 19A.25(1), 19A.38 and paragraphs 56 and 65(a) of Rule 19A.42 of the Listing Rules, and (ii) inclusion of the Mandatory Provisions and relevant ancillary provisions in the articles of association and relevant disclosure requirements in the [REDACTED] documents under Rule 19A.45 and Section 1 of Part D of Appendix 13 to the Listing Rules, are no longer necessary.

The Stock Exchange has published in February 2023 a consultation paper titled “Rule Amendments Following Mainland China Regulation Updates and Other Proposed Rule Amendments Relating to PRC Issuers” (the “**Consultation Paper**”) setting out the proposed amendments to the Listing Rules in light of the implementation of the New PRC Regulations (the “**Proposed Amendments**”), which have the effect of, among others, abolishing (i) the class meeting requirements for holders of domestic shares and H shares, and (ii) the requirement of including the Mandatory Provisions and relevant ancillary provisions in the articles of association and relevant disclosure requirements in the [REDACTED] documents, insofar as PRC issuers are concerned.

As a PRC issuer, we have formulated the Articles of Association by reference to the Guidelines on Articles. Pursuant to the Articles of Association, our [REDACTED] Shares (comprising Domestic Shares and [REDACTED] Foreign Shares) and H Shares are considered as one class of Shares, and there are no requirements for separate meetings of holders of [REDACTED] Shares and H Shares to be conducted. Further, the Mandatory Provisions, having been repealed, have not been adopted in the Articles of Association.

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As of the Latest Practicable Date, the Proposed Amendments had yet to be effective. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with Rules 19A.25(1), 19A.38, paragraphs 56 and 65(a) of Rule 19A.42, Rule 19A.45 and Section 1 of Part D of Appendix 13 to the Listing Rules, on the conditions that:

- (i) the Articles of Association are not inconsistent with the Guidelines on Articles and other applicable PRC laws and regulations;
- (ii) the Articles of Association are not inconsistent with (a) the Proposed Amendments as set out in the Consultation Paper, and (b) the other provisions of the Listing Rules that are not subject to the Proposed Amendments; and
- (iii) this document will be issued on or before [REDACTED].

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS

Please refer to the paragraphs headed “Business – Our Strategies” in this document for a detailed description of our future plans.

[REDACTED]

We estimate that the aggregate [REDACTED] to our Company from the [REDACTED] will be approximately HK\$[REDACTED], after deducting [REDACTED], fees and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any [REDACTED] and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per H Share.

We intend to apply such [REDACTED] from the [REDACTED] for the following purposes:

- (a) approximately [REDACTED], or HK\$[REDACTED], will be used for planned clinical trials, preparation for registration filings, and the planned commercial launch (including sales and marketing activities) of M701, our Core Product, of which
 - (i) approximately [REDACTED], or HK\$[REDACTED], will be used for planned clinical trials of M701 for the treatment of MA. We plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024.
 - (ii) approximately [REDACTED], or HK\$[REDACTED], will be used for planned clinical trials of M701 for the treatment of MPE. We plan to commence a pivotal/Phase III trial for M701 for the treatment of MPE in China in the third quarter of 2024.
 - (iii) approximately [REDACTED], or HK\$[REDACTED], will be used for the preparation for registration filings with the NMPA, planned commercial launch (including sales and marketing activities), and other regulatory matters for M701. We plan to submit the BLAs for M701 with the NMPA for the treatment of MA and MPE in the first quarter of 2025 and the fourth quarter of 2025, respectively. In addition, we plan to file the IND application for M701 with the NMPA for the treatment of solid tumor in the first quarter of 2024. In preparation for the commercial launch of M701, we will build an in-house commercialization team with medical and scientific background to maximize the reach of our product offering and expedite market acceptance of our products in China. We plan to market M701 through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians to promote the clinical use of M701. For more details, please refer to the paragraphs headed “Business – Commercialization” in this document. We also plan to make preparation for the commercial manufacturing of M701, which includes process transfer, sample production, process characterization and validation, and quality control.

FUTURE PLANS AND USE OF [REDACTED]

- (b) approximately [REDACTED], or HK\$[REDACTED], will be used for ongoing and planned clinical trials of Y101D, of which
 - (i) approximately [REDACTED], or HK\$[REDACTED], will be used for planned clinical trials of Y101D in combination therapy in treating pancreatic cancer. We commenced a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for pancreatic cancer patients in China in February 2023 and expect to complete this trial by the third quarter of 2024. Following the completion of this Phase Ib/II clinical trial, we also plan to commence a Phase III clinical trial in the fourth quarter of 2024 and expect to complete this trial by the second quarter of 2026.
 - (ii) approximately [REDACTED], or HK\$[REDACTED], will be used for planned clinical trials of Y101D in combination therapy in treating HCC and other advanced solid tumors. We commenced a Phase Ib/II clinical trial of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China in March 2023 and expect to complete this trial by the second quarter of 2025. Following the completion of this Phase Ib/II clinical trial, we also plan to commence a Phase III clinical trial.

We have executed an adaptive clinical development strategy and may evaluate and adjust our priorities and funding allocations for different indications or other aspects of our clinical trials for each drug candidate from time to time based on the status and results of ongoing clinical trials, while the percentages of [REDACTED] allocated to each drug candidate will generally remain stable. Therefore, the percentages and amounts of [REDACTED] allocated to each indication, clinical trial and/or commercialization plan of each drug candidate may be subject to change.

- (c) approximately [REDACTED], or HK\$[REDACTED], will be used for working capital and general corporate purposes.

We determine the above allocation of the [REDACTED] for our ongoing and planned clinical trials based on the anticipated expenses of these trials. We estimate such expenses based on the number of subjects expected to be enrolled and the average expense per subject expected to be incurred.

The number of subjects to be enrolled for our clinical trials is determined based on the anticipated trial designs, as well as various factors influencing these designs. For more details of the methodologies for determining the number of subjects to be enrolled for different types of our clinical trials, please refer to the paragraphs headed “Business – Our R&D Platform – Clinical Development – Clinical Trial Design and Implementation” in this document.

FUTURE PLANS AND USE OF [REDACTED]

Based on the historical expenses of our completed clinical trials and costs of comparable clinical trials of our industry peers, we estimate the average expense per subject for our cancer clinical trials to be ranging from HK\$400 thousand to HK\$633 thousand. The estimated average expenses per subject for clinical trials consist of six components, including CRO fees, clinical trial center fees, SMO fees, subject recruitment fees, drug costs, and testing fees. Among these six components, (a) CRO fees, clinical trial center fees, and SMO fees are primarily influenced by the rarity of the indication, treatment difficulty, and follow-up duration, (b) subject recruitment fees are mainly affected by the difficulty of enrolling subjects, (c) testing fees are primarily influenced by the testing items, (d) drug costs are mainly affected by drug production volume, transportation and storage difficulties, as well as the effects of economies of scale.

The estimated average expense per subject for our clinical trials is in line with that of similar drug candidates in similar clinical stages developed by the industry peers in China.

The above allocation of 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 estimated [REDACTED] range. If the [REDACTED] is set at HK\$[REDACTED] per H Share, being the high end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] to our Company will be increased to approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per H Share, being the low end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] to our Company will be decreased to approximately HK\$[REDACTED].

If the [REDACTED] is fully exercised, we will receive additional [REDACTED] of approximately HK\$[REDACTED] for [REDACTED] H Shares to be [REDACTED] and [REDACTED] upon the full exercise of the [REDACTED] based on the [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] range, and after deducting the [REDACTED] and [REDACTED] payable by us. The additional amount raised will be applied to the above areas of [REDACTED] on pro-rata basis.

If the [REDACTED] of the [REDACTED] are not immediately applied to the above purposes, we will only deposit those [REDACTED] into short-term interest-bearing accounts at licensed commercial banks and/or other authorised financial institutions (as defined under the applicable laws in the relevant jurisdictions).

To the extent that our [REDACTED] are not sufficient to fund the purposes set out above, we intend to fund the balance through a variety of means, including cash generated from operations, bank loans and other borrowings.

We will make 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]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

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[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report set out on pages I-1 to I-59, received from the Company’s reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this Document.

Deloitte.

德勤

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF WUHAN YZY BIOPHARMA CO., LTD., AND CHINA SECURITIES (INTERNATIONAL) CORPORATE FINANCE COMPANY LIMITED.

Introduction

We report on the historical financial information of Wuhan YZY Biopharma Co., Ltd.* (武漢友芝友生物製藥股份有限公司) (the “Company”) and its subsidiaries (collectively referred to as the “Group”) set out on pages I-4 to I-59, which comprises the consolidated statements of financial position of the Group as at December 31, 2021 and 2022, the statements of financial position of the Company as at December 31, 2021 and 2022, and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows of the Group for each of the two years ended December 31, 2022 (the “Track Record Period”) 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-4 to I-59 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [●], 2023 (the “Document”) in connection with the initial [REDACTED] of 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 to the Historical Financial Information, and for such internal control as the directors of the Company 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 (the “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.

* English name is for identification purpose only.

APPENDIX I

ACCOUNTANTS’ REPORT

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’ judgment, 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 the preparation set out in note 2 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 of the Company, 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 Group’s and the Company’s financial position as at December 31, 2021 and 2022 and of the Group’s financial performance and cash flows for the Track Record Period in accordance with the basis of preparation set out in note 2 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 preparation of 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 14 to the Historical Financial Information which states that no dividend was declared or paid by the Company in respect of the Track Record Period.

[Deloitte Touche Tohmatsu]

Certified Public Accountants

Hong Kong

[Date, 2023]

APPENDIX I

ACCOUNTANTS’ REPORT

HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The consolidated financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, have been prepared in accordance with the accounting policies which conform with International Financial Reporting Standards (“IFRSs”) issued by International Accounting Standards Board (“IASB”) and were audited by us in accordance with Hong Kong Standards on Auditing issued by the HKICPA (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.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended December 31,	
	<i>NOTES</i>	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Other income	7	12,798	2,560
Other gains and losses	8	716	671
Research and development expenses		(112,893)	(157,329)
Administrative expenses		(31,497)	(20,525)
[REDACTED] expenses		[REDACTED]	[REDACTED]
Finance costs	9	(14,972)	(2,468)
Loss before tax	10	(148,518)	(188,866)
Income tax expense	11	—	—
Loss and total comprehensive expenses for the year		(148,518)	(188,866)
Loss per share			
– Basic (RMB)	13	(0.98)	(1.10)
– Diluted (RMB)	13	(0.98)	N/A

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	NOTES	At December 31,	
		2021	2022
		RMB’000	RMB’000
Non-current assets			
Property and equipment	15	50,981	46,042
Right-of-use assets	16	8,982	8,507
Investment properties	17	581	536
Value added tax recoverable		13,822	8,671
Prepayment for acquisition of property and equipment		151	129
		<u>74,517</u>	<u>63,885</u>
Current assets			
Inventories	19	8,914	10,623
Prepayments, deposits and other receivables	20	14,139	27,814
Financial assets at fair value through profit or loss (“FVTPL”)	21	19,500	47,000
Cash and cash equivalents	22	83,085	153,520
		<u>125,638</u>	<u>238,957</u>
Current liabilities			
Trade and other payables	23	22,677	33,555
Bank borrowings	24	28,000	76,500
Amount due to a related party	25	4,659	–
Lease liabilities	26	397	169
Deferred income	27	1,175	2,975
Advance from transfer agreement	28	–	33,761
		<u>56,908</u>	<u>146,960</u>
Net current assets		<u>68,730</u>	<u>91,997</u>
Total assets less current liabilities		<u>143,247</u>	<u>155,882</u>
Non-current liabilities			
Lease liabilities	26	83	–
		<u>83</u>	<u>–</u>
Net assets		<u><u>143,164</u></u>	<u><u>155,882</u></u>
Capital and reserves			
Paid-in capital	30	165,072	–
Share capital	30	–	182,000
Reserves	31	(21,908)	(26,118)
Total equity		<u><u>143,164</u></u>	<u><u>155,882</u></u>

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ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	NOTES	At December 31,	
		2021	2022
		RMB’000	RMB’000
Non-current assets			
Property and equipment	15	50,981	46,042
Right-of-use assets	16	8,982	8,507
Investment properties	17	581	536
Investments in subsidiaries	18	21,000	21,000
Value added tax recoverable		13,822	8,230
Prepayment for acquisition of property and equipment		151	129
		<u>95,517</u>	<u>84,444</u>
Current assets			
Inventories	19	8,914	10,623
Prepayments, deposits and other receivables	20	14,139	25,808
Amount due from a subsidiary	25	–	17,418
Financial assets at fair value through profit or loss (“FVTPL”)	21	17,000	32,000
Cash and cash equivalents	22	82,262	152,982
		<u>122,315</u>	<u>238,831</u>
Current liabilities			
Trade and other payables	23	22,677	30,906
Bank borrowings	24	28,000	76,500
Amount due to a subsidiary	25	18,016	5,519
Amount due to a related party	25	4,659	–
Lease liabilities	26	397	169
Deferred income	27	1,175	2,975
Advance from transfer agreement	28	–	33,761
		<u>74,924</u>	<u>149,830</u>
Net current assets		<u>47,391</u>	<u>89,001</u>
Total assets less current liabilities		<u>142,908</u>	<u>173,445</u>
Non-current liabilities			
Lease liabilities	26	83	–
		<u>83</u>	<u>–</u>
Net assets		<u>142,825</u>	<u>173,445</u>
Capital and reserves			
Paid-in capital	30	165,072	–
Share capital	30	–	182,000
Reserves	31	(22,247)	(8,555)
Total equity		<u>142,825</u>	<u>173,445</u>

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Paid-in capital	Share capital	Capital reserve	Share premium	Other reserves	Share-based payment reserve	Accumulated losses	Total
	RMB'000 (note 30)	RMB'000 (note 30)	RMB'000	RMB'000	RMB'000 (note)	RMB'000	RMB'000	RMB'000
At January 1, 2021	156,392	–	293,198	–	(105,047)	48,632	(423,918)	(30,743)
Loss and total comprehensive expenses for the year	–	–	–	–	–	–	(148,518)	(148,518)
Contribution from Series A Investors	–	–	4,700	–	–	–	–	4,700
Debt waived by Series A Investors (note 33)	–	–	14,100	–	–	–	–	14,100
Issue of Series B shares-second and third tranche (note 30)	943	–	50,767	–	–	–	–	51,710
Issue of Series B+ shares (note 30)	1,886	–	18,114	–	–	–	–	20,000
Issue of Series B++ shares (note 30)	5,851	–	67,649	–	–	–	–	73,500
Recognition of liabilities on Series B, Series B+ and Series B++ shares (note 29)	–	–	–	–	(134,042)	–	–	(134,042)
Termination of redemption liabilities on Series B, Series B+, and Series B++ shares (note 29)	–	–	–	–	252,811	–	–	252,811
Recognition of equity-settled share-based payment (note 32)	–	–	–	–	–	39,646	–	39,646
At December 31, 2021	165,072	–	448,528	–	13,722	88,278	(572,436)	143,164
Loss and total comprehensive expenses for the year	–	–	–	–	–	–	(188,866)	(188,866)
Conversion into a joint stock company (note 30)	(165,072)	168,000	(448,528)	7,384	(13,722)	(88,278)	540,216	–
Issue of shares (note 30)	–	14,000	–	186,000	–	–	–	200,000
Recognition of equity-settled share-based payment (note 32)	–	–	–	–	–	1,584	–	1,584
At December 31, 2022	–	182,000	–	193,384	–	1,584	(221,086)	155,882

Note: Other reserve mainly comprises recognition and termination of redemption liabilities on ordinary shares as disclosed in note 29.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
OPERATING ACTIVITIES		
Loss before tax	(148,518)	(188,866)
Adjustments for:		
Gain from changes in fair value of financial assets at FVTPL	(1,261)	(671)
Bank interest income	(162)	(283)
Loss on disposal of property and equipment	545	3
Depreciation of property and equipment	6,983	6,299
Depreciation of right-of-use assets	589	600
Depreciation of investment properties	45	45
Share-based payment expenses	39,646	1,584
Finance costs	14,972	2,468
Operating cash flow before movements in working capital	(87,161)	(178,821)
Increase in prepayments, deposits, and other receivables	(8,817)	(7,930)
(Increase) decrease in value added tax recoverable	(6,075)	5,151
Increase in inventories	(515)	(1,709)
Increase in deferred income	251	1,800
Increase in trade and other payables	449	9,465
Increase (decrease) in amount due to a related party	3,158	(4,659)
Cash used in operations	(98,710)	(176,703)
Income tax paid	—	—
NET CASH USED IN OPERATING ACTIVITIES	(98,710)	(176,703)

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	Year ended December 31,	
	2021	2022
	RMB'000	RMB'000
INVESTING ACTIVITIES		
Interest received from banks	162	283
Proceeds from disposal of property and equipment	47	–
Advance from transfer agreement	–	33,761
Gains on financial assets at FVTPL	1,261	671
Purchase of property and equipment	(1,903)	(1,411)
Purchase of financial assets at FVTPL	(481,600)	(378,500)
Redemption of financial assets at FVTPL	462,100	351,000
NET CASH (USED IN) FROM INVESTING ACTIVITIES	(19,933)	5,804
FINANCING ACTIVITIES		
Contribution from Series A Investors	4,700	–
Proceeds from issue of Series B shares-first tranche	–	–
Proceeds from issue of Series B shares-second tranche	51,710	–
Proceeds from issue of Series B+ shares	20,000	–
Proceeds from issue of Series B++ shares	73,500	–
Proceeds from issue of shares	–	200,000
New bank borrowing raised	28,000	76,500
Repayment of bank borrowings	(21,000)	(28,000)
Repayment of borrowings from shareholders	(71,070)	–
Payments of lease liabilities	(411)	(436)
[REDACTED] paid	[REDACTED]	[REDACTED]
Interest paid	(3,956)	(2,448)
Interest paid on lease liabilities	(42)	(20)
NET CASH FROM FINANCING ACTIVITIES	81,034	241,334
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(37,609)	70,435
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	120,694	83,085
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	83,085	153,520

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NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. GENERAL INFORMATION

The Company was established in the People’s Republic of China (the “PRC”) on July 8, 2010 as a limited liability company. On January 13, 2022, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC, with its name changed to from Wuhan YZY Biopharma Limited Company (武漢友芝友生物製藥有限公司) to Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司). The respective address of the registered office and the principal place of business of the Company are set out in the section headed “Corporate Information” to the document dated [●] 2023 (the “Document”).

The principal activities of the Company and its subsidiaries (“the Group”) are mainly committed to develop bispecific antibody (BsAb)-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. Particulars and principal activities of the subsidiaries are disclosed in note 38.

The functional currency of the Company and its subsidiaries is RMB, which is the same as the presentation currency of the Historical Financial Information.

2. BASIS OF PREPARATION OF THE HISTORICAL FINANCIAL INFORMATION

The Historical Financial Information has been prepared based on the accounting policies set out in note 4 which conform with IFRSs issued by the IASB.

The statutory financial statements of the Company for the years ended December 31, 2021 and 2022 were prepared in accordance with the Accounting Standards for Business Enterprises issued by the Ministry of Finance of the PRC and were audited by Wuhan Dongchen Certified Public Accountants LLP* (武漢東晨會計師事務所(特殊普通合伙)), a certified public accountant registered in the PRC.

3. APPLICATION OF NEW AND AMENDMENTS TO IFRSs

For the purpose of preparing and presenting the Historical Financial Information for the Track Record Period, the Group has consistently applied the accounting policies which conform with IFRSs, which are effective for the accounting period beginning on January 1, 2022, throughout the Track Record Period.

New and amendments to IFRSs in issue but not yet effective

At the date of this report, the following new and amendments to IFRSs have been issued which are not yet effective:

IFRS 17 (including the June 2020 and December 2021 Amendments to IFRS 17)	Insurance Contracts ¹
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ³
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback ⁴
Amendments to IAS 1	Classification of Liabilities as Current or Non-current ⁴
Amendments to IAS 1	Non-current Liabilities with Covenants ⁴
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies ¹
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements ⁴
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
Amendments to IAS 12	International Tax Reform – Pillar Two Model Rules ²

- Effective for annual periods beginning on or after January 1, 2023.
- Effective for annual periods beginning on or after 1 January 2023 (except for paragraphs 4A and 88A of IAS 12 which are immediately effective upon issue of the amendments).
- Effective for annual periods beginning on or after a date to be determined.
- Effective for annual periods beginning on or after 1 January 2024.

* English name is for identification purpose only.

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The directors of the Company anticipate that the application of these new and amendments to IFRSs will have no material impact on the Group’s financial position and performance when they become effective.

4. SIGNIFICANT ACCOUNTING POLICIES

The Historical Financial Information has been prepared in accordance with the following accounting policies which conform with IFRSs issued by the IASB. For the purpose of preparation of the Historical Financial Information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the Historical Financial Information includes the applicable disclosures required by the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and by the Hong Kong Companies Ordinance.

The Historical Financial Information has been prepared on the historical cost basis except for certain financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

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, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, the Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value for measurement and/or disclosure purposes in the Historical Financial Information is determined on such a basis, except for share-based payment transactions that are within the scope of IFRS 2 *Share-based Payment*, leasing transactions that are accounted for in accordance with IFRS 16 *Leases*, and measurements that have some similarities to fair value but are not fair value, such as net realizable value in IAS 2 *Inventories* or value in use in IAS 36 *Impairment of Assets*.

In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

The principal accounting policies are set out below.

Basis of consolidation

The Historical Financial Information incorporates the financial statements of the Company and its subsidiaries. Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

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 listed above.

Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statements of profit or loss and other comprehensive income from the date the Group gains control until the date when the Group ceases to control the subsidiary.

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When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies in line with the Group’s accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Investments in subsidiaries

Investments in subsidiaries are included in the statements of financial position of the Company at cost less any identified impairment losses.

Leases

Definition of 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.

For contracts entered into or modified on or after the date of initial application of IFRS 16, the Group assesses whether a contract is or contains a lease based on the definition under IFRS 16 at inception or modification date, as appropriate. Such contract will not be reassessed unless the terms and conditions of the contract are subsequently changed.

The Group as a lessee

Allocation of consideration to components of a contract

For a contract that contains a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

Non-lease components are separated from lease component and are accounted for by applying other applicable standards.

Short-term leases

The Group applies the short-term lease recognition exemption to 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 recognized as expense on a straight-line basis over the lease term.

Right-of-use assets

The cost of right-of-use asset includes:

- the amount of the initial measurement of the lease liability; and
- any lease payments made at or before the commencement date, less any lease incentives received;

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

The Group presents right-of-use assets as a separate line item on the consolidated statements of financial position.

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Refundable rental deposits

Refundable rental deposits paid are accounted under IFRS 9 *Financial Instruments* (“IFRS 9”) and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments and included in the cost of right-of-use assets.

Lease liabilities

At the commencement date of a lease, the Group recognizes and measures the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments are fixed payments (including in-substance fixed payments) less any lease incentives receivable.

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

The Group remeasures lease liabilities (and makes a corresponding adjustment to the related right-of-use assets) whenever the lease term has changed or there is a change in the assessment of exercise of a purchase option, in which case the related lease liability is remeasured by discounting the revised lease payments using a revised discount rate at the date of reassessment.

The Group presents lease liabilities as a separate line item on the consolidated statements of financial position.

Lease modifications

The Group accounts for a lease modification as a separate lease if:

- the modification increases the scope of the lease by adding the right to use one or more underlying assets; and
- the consideration for the leases increases by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the circumstances of the particular contract.

For a lease modification that is not accounted for as a separate lease, the Group remeasures the lease liability based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

The Group accounts for the remeasurement of lease liabilities by making corresponding adjustments to the relevant right-of-use asset. When the modified contract contains a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the modified contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

The Group as a lessor

Classification and measurement of leases

Leases for which the Group is a lessor are classified as finance or operating leases. Whenever the terms of the lease transfer substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee, the contract is classified as a finance lease. All other leases are classified as operating leases.

Rental income from operating leases is recognized in profit or loss on a straight-line basis over the term of the relevant lease. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset, and such costs are recognized as an expense on a straight-line basis over the lease term.

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Refundable rental deposits

Refundable rental deposits received are accounted for under IFRS 9 and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments from lessees.

Foreign currencies

In preparing the financial statements of each individual group entity, transactions in currencies other than the functional currency of that entity (foreign currencies) are recognized at the rates of exchanges prevailing on the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognized in profit or loss in the period in which they arise.

Borrowing costs

All borrowing costs not directly attributable to the acquisition, construction or production of qualifying assets are recognized in profit or loss in the period in which they are incurred.

Government grants

Government grants are not recognized until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that the Group should purchase, construct or otherwise acquire non-current assets are recognized as deferred income in the consolidated statements of financial position and transferred to profit or loss on a systematic and rational basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under “other income”.

Employee benefits

Retirement benefit costs

The Group participates in state-managed retirement benefit schemes, which are defined contribution schemes, pursuant to which the Group pays a fixed percentage of staff’s wages as contributions to the plans. Payments to such retirement benefit schemes are recognized as an expense when employees have rendered service entitling them to the contributions.

Short-term employee benefits

Short-term employee benefits are recognized at the undiscounted amount of the benefits expected to be paid as and when employees rendered the services. All short-term employee benefits are recognized as an expense unless another IFRS requires or permits the inclusion of the benefit in the cost of an asset.

A liability is recognized for benefits accruing to employees (such as wages and salaries, and annual leave) after deducting any amount already paid.

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Share-based payment

Equity-settled share-based payment transactions

Share options/restricted shares (“RS”) granted to employees

Equity-settled share-based payments to employees are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on the Group’s estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payment reserve). At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve. For RS that vest immediately at the date of grant, the fair value of the RS granted is expensed immediately to profit or loss.

Modification to the terms and conditions of the share-based payment arrangements

When the terms and conditions of an equity-settled share-based payment arrangement are modified, the Group recognizes, as a minimum, the services received measured at the grant date fair value of the equity instruments granted, unless those equity instruments do not vest because of failure to satisfy a vesting condition (other than a market condition) that was specified at grant date. In addition, if the Group modifies the vesting conditions (other than a market condition) in a manner that is beneficial to the employees, for example, by reducing the vesting period, the Group takes the modified vesting conditions into consideration over the remaining vesting period.

The incremental fair value granted, if any, is the difference between the fair value of the modified equity instruments and that of the original equity instruments, both estimated as at the date of modification.

If the modification occurs during the vesting period, the incremental fair value granted is included in the measurement of the amount recognized for services received over the period from modification date until the date when the modified equity instruments are vested, in addition to the amount based on the grant date fair value of the original equity instruments, which is recognized over the remainder of the original vesting period.

If the modification occurs after vesting period, the incremental fair value granted is recognized immediately, or over the vesting period if additional period of service is required before the modified equity instruments are vested.

If the modification reduces the total fair value of the share-based arrangement, or is not otherwise beneficial to the employee, the Group continues to account for the original equity instruments granted as if that modification had not occurred.

Taxation

Income tax expense represents the sum of the tax currently payable and deferred tax.

The tax currently payable is based on taxable profit for the year. Taxable profit differs from loss before tax because of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group’s liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of each reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the Historical Financial Information and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognized for all taxable temporary differences. Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets and liabilities are not recognized if the temporary difference arises from the initial recognition of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

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Deferred tax liabilities are recognized for taxable temporary differences associated with investments in subsidiaries, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with such investments are only recognized to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

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 profits will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset is realized, based on tax rate (and tax laws) that have been enacted or substantively enacted by the end of each reporting period.

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of each reporting period, to recover or settle the carrying amount of its assets and liabilities.

For the purposes of measuring deferred tax for leasing transactions in which the Group recognizes the right-of-use assets and the related lease liabilities, the Group first determines whether the tax deductions are attributable to the right-of-use assets or the lease liabilities.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 *Income Taxes* requirements to the leasing transaction as a whole. Temporary differences relating to right-of-use assets and lease liabilities are assessed on a net basis. Excess of depreciation on right-of-use assets over the lease payments for the principal portion of lease liabilities results in net deductible temporary differences.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income tax levied to the same taxable entity by the same taxation authority.

Current and deferred tax are recognized in profit or loss.

Property and equipment

Property and equipment are tangible assets that are held for use in supply of services, or for administrative purposes other than construction in progress. Property and equipment are stated in the consolidated statements of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

Properties in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management, including costs of testing whether the related assets is functioning properly. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

When the Group makes payments for ownership interests of properties which includes both leasehold land and building elements, the entire consideration is allocated between the leasehold land and the building elements in proportion to the relative fair values at initial recognition. To the extent the allocation of the relevant payments can be made reliably, interest in leasehold land is presented as “right-of-use assets” in the consolidated statements of financial position. When the consideration cannot be allocated reliably between non-lease building element and undivided interest in the underlying leasehold land, the entire properties are classified as property and equipment.

Depreciation is recognized so as to write off the cost of assets other than properties under construction less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

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An item of property and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

Investment properties

Investment properties are properties held to earn rentals and/or for capital appreciation.

Investment properties are initially measured at cost, including any directly attributable expenditure. Subsequent to initial recognition, investment properties are stated at cost less subsequent accumulated depreciation and any accumulated impairment losses. Depreciation is recognized so as to write off the cost of investment properties over their estimated useful lives and after taking into account of their estimated residual value, using the straight-line method.

An investment property is derecognized upon disposal or when the investment property is permanently withdrawn from use and no future economic benefits are expected from its disposals. Any gain or loss arising on derecognition of the property (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the profit or loss in the period in which the property is derecognized.

Intangible assets

Internally-generated intangible assets-research and development expenditure

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible assets so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible assets;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

An intangible asset is derecognized on disposal, or when no future economic benefits are expected from use or disposal. Gains and losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognized in profit or loss when the asset is derecognized.

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Impairment on property and equipment, investment properties and right-of-use assets

At the end of each reporting period, the Group reviews the carrying amounts of its property and equipment, investment properties and right-of-use assets to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any).

The recoverable amount of property and equipment, investment properties and right-of-use assets are estimated individually. When it is not possible to estimate the recoverable amount individually, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. 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 (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, the Group compares the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

Cash and cash equivalents

Cash and cash equivalents presented on the consolidated statements of financial position include:

- (a) cash, which comprises of cash on hand and demand deposits, excluding bank balances that are subject to regulatory restrictions that result in such balances no longer meeting the definition of cash; and
- (b) cash equivalents, which comprises of short-term (generally with original maturity of three months or less), highly liquid investments that are readily convertible to a known amount of cash and which are subject to an insignificant risk of changes in value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

For the purposes of the consolidated statements of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

Inventories

Inventories are stated at the lower of cost and net realizable value. Costs of inventories are determined on a weighted average method. Net realizable value represents the estimate selling price for inventories less all estimated costs of completion and costs necessary to make the sale. Costs necessary to make the sale include incremental costs directly attributable to the sale and non-incremental costs which the Group must incur to make the sale.

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Contingent liabilities

A contingent liability is a present obligation arising from past events but is not recognized because it is not probable that an outflow of resources embodying economic benefits will be required to settle the obligation or the amount of the obligation cannot be measured with sufficient reliability.

Where the Group is jointly and severally liable for an obligation, the part of the obligation that is expected to be met by other parties is treated as a contingent liability and it is not recognized in the consolidated financial statements.

The Group assesses continually to determine whether an outflow of resources embodying economic benefits has become probable. If it becomes probable that an outflow of future economic benefits will be required for an item previously dealt with as a contingent liability, a provision is recognized in the consolidated financial statements in the reporting period in which the change in probability occurs, except in the extremely rare circumstances where no reliable estimate can be made.

Financial instruments

Financial assets and financial liabilities are recognized when a group entity becomes a party to the contractual provisions of the instrument. All regular way purchases or sales of financial assets are recognized and derecognized on a trade date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the market place.

Financial assets and financial liabilities are initially measured at fair value. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets and financial liabilities at FVTPL) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributed to the acquisition of financial assets or financial liabilities at FVTPL are recognized immediately in profit or loss.

The effective interest method is a method of calculating the amortized cost of a financial asset or financial liability and of allocating interest income and interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts and payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial asset or financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

Financial assets

Classification and subsequent measurement of financial assets

Financial assets that meet the following conditions are subsequently measured at amortized cost:

- the financial asset is held within a business model whose objective is to collect contractual cash flows; and
- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

All other financial assets the Group hold are subsequently measured at FVTPL.

Amortized cost and interest income

Interest income is recognized using the effective interest method for financial assets measured subsequently at amortized cost and calculated by applying the effective interest rate to the gross carrying amount of a financial asset except for financial assets that have subsequently become credit-impaired (see below). For financial assets that have subsequently become credit-impaired, interest income is recognized by applying the effective interest rate to the amortized cost of the financial asset from the next reporting period. If the credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognized by applying the effective interest rate to the gross carrying amount of the financial asset from the beginning of the reporting period following the determination that the asset is no longer credit-impaired.

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Financial assets at FVTPL

Financial assets that do not meet the criteria for being measured at amortized cost or fair value through other comprehensive income are measured at FVTPL.

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. The net gain or loss recognized in profit or loss includes any interest earned on the financial asset and is included in the “other gains and losses” line item.

Impairment of financial assets

The Group performs impairment assessment under expected credit losses (“ECL”) model on financial assets (including deposits and other receivables and cash and cash equivalents) which are subject to impairment under IFRS 9. The amount of ECL is updated at each reporting dates to reflect changes in credit risk since initial recognition.

Lifetime ECL represents the ECL that will result from all possible default events over the expected life of the relevant instrument. In contrast, 12-month ECL (“12m ECL”) represents the portion of lifetime ECL that is expected to result from default events that are possible within 12 months after each reporting date. Assessment are done based on the Group’s historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current conditions at the reporting date as well as the forecast of future conditions.

The Group measures the loss allowance equal to 12m ECL for its financial instruments, unless there has been a significant increase in credit risk since initial recognition, in which case the Group recognizes lifetime ECL. The assessment of whether lifetime ECL should be recognized is based on significant increases in the likelihood or risk of a default occurring since initial recognition.

(i) Significant increase in credit risk

In assessing whether the credit risk has increased significantly since initial recognition, the Group compares the risk of a default occurring on the financial instrument as at each reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition. In making this assessment, the Group considers both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly:

- an actual or expected significant deterioration in the financial instrument’s external (if available) or internal credit rating;
- significant deterioration in external market indicators of credit risk, e.g. a significant increase in the credit spread, the credit default swap prices for the debtor;
- existing or forecast adverse changes in business, financial or economic conditions that are expected to cause a significant decrease in the debtor’s ability to meet its debt obligations;
- an actual or expected significant deterioration in the operating results of the debtor;
- an actual or expected significant adverse change in the regulatory, economic, or technological environment of the debtor that results in a significant decrease in the debtor’s ability to meet its debt obligations.

Irrespective of the outcome of the above assessment, the Group presumes that the credit risk has increased significantly since initial recognition when contractual payments are more than 30 days past due, unless the Group has reasonable and supportable information that demonstrates otherwise.

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The Group regularly monitors the effectiveness of the criteria used to identify whether there has been a significant increase in credit risk and revises them as appropriate to ensure that the criteria are capable of identifying significant increase in credit risk before the amount becomes past due.

(ii) Definition of default

For internal credit risk management, the Group considers an event of default occurs when information developed internally or obtained from external sources indicates that the debtor is unlikely to pay its creditors, including the Group, in full (without taking into account any collaterals held by the Group).

Irrespective of the above, the Group considers that default has occurred when a financial asset is more than 90 days past due unless the Group has reasonable and supportable information to demonstrate that a more lagging default criterion is more appropriate.

(iii) Credit-impaired financial assets

A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. Evidence that a financial asset is credit-impaired includes observable data about the following events:

- (a) significant financial difficulty of the issuer or the borrower;
- (b) a breach of contract, such as a default or past due event;
- (c) the lender(s) of the borrower, for economic or contractual reasons relating to the borrower’s financial difficulty, having granted to the borrower a concession(s) that the lender(s) would not otherwise consider; or
- (d) it is becoming probable that the borrower will enter bankruptcy or other financial reorganization.

(iv) Write-off policy

The Group writes off a financial asset when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, for example, when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings. Financial assets written off may still be subject to enforcement activities under the Group’s recovery procedures, taking into account legal advice where appropriate. A write-off constitutes a derecognition event. Any subsequent recoveries are recognized in profit or loss.

(v) Measurement and recognition of ECL

The measurement of ECL is a function of the probability of default, loss given default (i.e. the magnitude of the loss if there is a default) and the exposure at default. The assessment of the probability of default and loss given default is based on historical data adjusted by forward-looking information. Estimation of ECL reflects an unbiased and probability-weighted amount that is determined with the respective risks of default occurring as the weights.

Generally, the ECL is the difference between all contractual cash flows that are due to the Group in accordance with the contract and the cash flows that the Group expects to receive, discounted at the effective interest rate determined at initial recognition.

Interest income is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit impaired, in which case interest income is calculated based on amortized cost of the financial asset.

The Group recognizes an impairment gain or loss in profit or loss for all financial instruments by adjusting their carrying amount, with the exception of deposits and other receivables, where the corresponding adjustment is recognized through a loss allowance account.

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Derecognition of financial assets

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the assets expire.

On derecognition of a financial asset measured at amortized cost, the difference between the asset’s carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

Financial liabilities and equity

Classification as debt or equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct [REDACTED].

Financial liabilities

All financial liabilities are subsequently measured at amortized cost using the effective interest method.

Financial liabilities at amortized cost

Financial liabilities including trade and other payables, bank borrowings, amount due to a subsidiary, amount due to a related party and redemption liabilities on ordinary shares are subsequently measured at amortized cost, using the effective interest method.

Redemption liabilities on ordinary shares

For the redeemable obligation on certain ordinary shares issued by the Company as detailed in note 29, financial liabilities are recognized for the Company to purchase its own equity instruments for cash and measured at the present value of the redemption amount. The debit recognized in equity on initial recognition is presented as “other reserves”. The financial liabilities are subsequently measured at amortized cost, of which interest is accrued in accordance with the effective interest method in profit or loss. When the redemption rights related to the ordinary shares are terminated, redemption liabilities on ordinary shares are extinguished and credited to equity.

Derecognition of financial liabilities

The Group derecognizes financial liabilities when, and only when, the Group’s obligations are discharged, canceled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

5. CRITICAL ACCOUNTING JUDGMENTS AND KEY SOURCE OF ESTIMATION UNCERTAINTIES

In the application of the Group’s accounting policies, which are described in note 4, the directors of the Company are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

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Critical judgments in applying accounting policies

The following are the critical judgments, apart from those involving estimations (see below), that the directors of the Company have made in the process of applying the Group’s accounting policies and that have the most significant effect on the amounts recognized in the Historical Financial Information.

Research and development expenses

Development expenses incurred on the Group’s drug product pipelines are capitalized and deferred only when the Group can demonstrate (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale; (ii) the Group’s intention to complete and the Group’s ability to use or sell the asset; (iii) how the asset will generate future economic benefits; (iv) the availability of resources to complete the pipeline; and (v) the ability to measure reliably the expenditure during the development. Research and development expenses which do not meet these criteria are expensed when incurred. Management assesses the progress of each of the research and development projects and determine whether the criteria are met for capitalization. During the Track Record Period, all research and development costs are expensed when incurred.

Key sources of estimation uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty at the end of each reporting periods, that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the coming twelve months, are described below.

Useful lives of property and equipment

The management of the Group determines the estimated useful lives and the depreciation method in determining the related depreciation charges for its property and equipment. This estimate is reference to the useful lives of property and equipment of similar nature and functions in the industry. Management will increase the depreciation charge where useful lives are expected to be shorter than expected, or will write off or write down obsolete assets that have been abandoned or sold.

6. SEGMENT INFORMATION

The Group has been operating in one reportable segment, being the discovering, developing and commercializing new class of innovative medicines in respect to anti-tumor bispecific antibody.

For the purpose of resource allocation and performance assessment, the Group’s chief executive officer, being the chief operating decision maker (“CODM”), reviews the overall results and financial position of the Group as a whole and no further analysis of the single segment is presented.

Geographical information

The Group has not generated any revenue during the Track Record Period. As at December 31, 2021 and 2022, all of the Group’s non-current assets are located in the PRC.

7. OTHER INCOME

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Government grants (<i>note i</i>)	12,093	2,254
Income from sales of protein antigen (<i>note ii</i>)	472	–
Bank interest income	162	283
Others	71	23
	<u>12,798</u>	<u>2,560</u>

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Notes:

- (i) The amounts represent government grants received from various PRC government authorities as incentives for the Group’s research and development activities. Some subsidies had certain conditions imposed by the respective PRC government authorities. The relevant conditions have been fully met upon recognition.
- (ii) The amounts represent sales of protein antigen to a single customer. Sales of protein antigen is not derived from the ordinary course of the Group. For sales of protein antigen, income is recognized when the customer obtains control of the goods, being at the point the goods are delivered to the customer. The Group requires for 100% upfront payments from its customers.

8. OTHER GAINS AND LOSSES

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Loss on disposal of property and equipment	(545)	(3)
Gain from changes in fair value of financial assets at FVTPL (note 21)	1,261	671
Others	—	3
	<u>716</u>	<u>671</u>

9. FINANCE COSTS

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Interest expenses on bank and other borrowings	1,208	2,448
Interest expenses on lease liabilities	42	20
Interest expenses on redemption liabilities on ordinary shares (note 29)	13,722	—
	<u>14,972</u>	<u>2,468</u>

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10. LOSS BEFORE TAX

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Loss before tax for the year		
has been arrived at after charging:		
Directors and supervisors’ emoluments (<i>note 12</i>)	20,859	4,906
Other staff costs:		
– salaries and other benefits	15,892	20,640
– discretionary bonuses (<i>note</i>)	1,314	2,719
– retirement benefit scheme contributions	2,177	3,337
– share-based payments	23,151	1,584
	<u>63,393</u>	<u>33,186</u>
Depreciation of property and equipment	6,983	6,299
Depreciation of right-of-use assets	589	600
Depreciation of investment properties	<u>45</u>	<u>45</u>
	<u>7,617</u>	<u>6,944</u>
Cost of inventories recognized as an expense	17,595	21,481
[REDACTED] expenses	<u>[REDACTED]</u>	<u>[REDACTED]</u>

Note: Discretionary bonuses are determined based on the duties and performances of the relevant individuals and the operating result of the Group.

11. INCOME TAX EXPENSE

Pursuant to the law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulations of the EIT Law, the applicable tax rate of the Company and its subsidiaries is 25% during the Track Record Period.

The tax charge for the Track Record Period can be reconciled to the loss before tax per the consolidated statements of profit or loss and other comprehensive expenses as follows:

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Loss before tax	(148,518)	(188,866)
Income tax expense		
calculated at 25%	(37,130)	(47,217)
Tax effect of expenses that are not deductible for tax purpose	14,163	1,730
Effect of research and development expenses that are additionally deducted (<i>note</i>)	(4,990)	(18,526)
Tax effect of deductible temporary differences not recognized	1,379	2,247
Tax effect of tax losses not recognized	<u>26,578</u>	<u>61,766</u>
	<u>–</u>	<u>–</u>

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Note: Pursuant to Caishui 2018 circular No. 99, the Group enjoys super deduction of 175% on qualifying research and development expenditures throughout the Track Record Period.

At December 31, 2021 and 2022, the Group has unrecognized tax losses of approximately RMB427,944,000 and RMB632,811 respectively. At December 31, 2021 and 2022, the Group has deductible temporary differences of approximately RMB7,268,000 and RMB16,256,000 respectively. No deferred tax asset has been recognized in respect of the tax losses or temporary differences due to the unpredictability of future profit streams.

The unrecognized tax losses will be carried forward and expire in years as follows:

	At December 31,	
	2021	2022
	RMB'000	RMB'000
2022	42,197	–
2023	44,222	44,222
2024	117,457	117,457
2025	117,756	117,756
2026	106,312	106,312
2027	–	247,064
	<u>427,944</u>	<u>632,811</u>

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12. DIRECTORS’, SUPERVISORS’, AND CHIEF EXECUTIVE OFFICER’S EMOLUMENTS AND FIVE HIGHEST PAID EMPLOYEES

Details of the emoluments paid or payable to the directors, supervisors and the Chief Executive Officer of the Company for the service provided to the Group during the Track Record Period are as follows:

(a) Executive and non-executive directors and supervisors

	Salaries and other benefits	Retirement benefit scheme contributions	Share-based payments	Discretionary bonuses	Total
	RMB’000	RMB’000	RMB’000 (note xv)	RMB’000 (note xiii)	RMB’000
For the year ended December 31, 2021					
<i>Chief Executive Officer and executive director:</i>					
Mr. Pengfei Zhou (note i)	1,825	39	10,814	157	12,835
<i>Non-executive directors:</i>					
Mr. Xiwu Hui (惠希武) (note ii)	—	—	—	—	—
Mr. Qian Liang (梁倩) (note ii)	—	—	—	—	—
Mr. Qian Yuan (袁謙) (note iii)	—	—	—	—	—
Mr. Hongfeng Zhou (周宏峰) (note iii)	—	—	—	—	—
Mr. Zhenhai Pang (龐振海) (note iv)	—	—	—	—	—
Mr. Dan Liu (柳丹) (note v)	—	—	—	—	—
Mr. Hongwei Guo (郭宏偉) (note vi)	—	—	—	—	—
Mr. Shouwu Xie (謝守武) (note vi)	—	—	—	—	—
<i>Supervisors:</i>					
Mr. Jing Zhang (張敬) (note vii)	637	24	3,594	94	4,349
Mr. Jumin Sun (孫聚民) (note x)	—	—	—	—	—
Mr. Fang Liu (劉芳) (note xi)	—	—	—	—	—
Mr. Changtao Ji (紀昌濤) (note ix)	—	—	—	—	—
Mr. Jizu Yi (note viii)	1,450	—	2,087	138	3,675
	<u>3,912</u>	<u>63</u>	<u>16,495</u>	<u>389</u>	<u>20,859</u>

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	Salaries and other benefits	Retirement benefit scheme contributions	Share-based payments	Discretionary bonuses	Total
	RMB'000	RMB'000	RMB'000 (note xv)	RMB'000 (note xiii)	RMB'000
For the year ended					
December 31, 2022					
<i>Chief Executive Officer</i>					
<i>and executive director:</i>					
Mr. Pengfei Zhou (note i)	1,989	52	—	267	2,308
<i>Non-executive directors:</i>					
Mr. Xiwu Hui					
(惠希武) (note ii)	—	—	—	—	—
Mr. Qian Liang (梁倩)					
(note ii)	—	—	—	—	—
Mr. Qian Yuan (袁謙)					
(note iii)	—	—	—	—	—
Mr. Hongfeng Zhou					
(周宏峰) (note iii)	—	—	—	—	—
Mr. Zhenhai Pang					
(龐振海) (note iv)	—	—	—	—	—
Mr. Dan Liu (柳丹)					
(note v)	—	—	—	—	—
Mr. Hongwei Guo					
(郭宏偉) (note vi)	—	—	—	—	—
Mr. Shouwu Xie (謝守武)					
(note vi)	—	—	—	—	—
<i>Supervisors:</i>					
Mr. Jing Zhang (張敬)					
(note vii)	694	51	—	103	848
Mr. Jumin Sun (孫聚民)					
(note x)	—	—	—	—	—
Ms. Fang Liu (劉芳)					
(note xi)	—	—	—	—	—
Mr. Changtao Ji (紀昌濤)					
(note ix)	—	—	—	—	—
Mr. Jizu Yi (note viii)	1,581	—	—	169	1,750
	<u>4,264</u>	<u>103</u>	<u>—</u>	<u>539</u>	<u>4,906</u>

Notes:

- i. Mr. Pengfei Zhou was appointed as the chief executive officer on March 16, 2018 and executive director on November 11, 2022.
- ii. Mr. Xiwu Hui and Mr. Qian Liang were appointed as non-executive directors of the Company on November 11, 2022.
- iii. Mr. Qian Yuan and Mr. Hongfeng Zhou were appointed as non-executive directors of the Company on November 11, 2022.
- iv. Mr. Zhenhai Pang was appointed as non-executive director of the Company on November 11, 2022.
- v. Mr. Dan Liu was appointed as non-executive director of the Company on November 11, 2022.

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- vi. Mr. Hongwei Guo and Mr. Shouwu Xie was appointed as non-executive director of the Company on November 11, 2022.
- vii. Mr. Jing Zhang was appointed as supervisor of the Company on February 26, 2018. The supervisor’s emoluments disclosed above was for service rendered by him as employee of the Company.
- viii. Mr. Jizu Yi was appointed as supervisor of the Company on May 25, 2021. The supervisor’s emoluments disclosed above was for service rendered by him as employee of the Company.
- ix. Mr. Changtao Ji was appointed as supervisor of the Company on May 20, 2021.
- x. Mr. Jumin Sun was appointed as supervisor of the Company on January 10, 2018.
- xi. Ms. Fang Liu was appointed as supervisor of the Company on March 7, 2016.
- xii. The executive director’s emoluments shown above was for his services in connection with the management of the affairs of the Company and the Group.
- xiii. The discretionary bonuses are determined based on the duties and performances of the relevant individuals and the operating result of the Group.
- xiv. None of the directors of the Company waived or agreed to waive any emoluments during the Track Record Period.
- xv. During the Track Record Period, certain directors and supervisors were granted share options or restricted shares, in respect of their services to the Group, details are set out in note 32 to the Historical Financial Information.

(b) Independent non-executive directors

No independent non-executive directors were appointed by the Company during the Track Record Period. Weiguo Dai, Bin Cheng (程斌), Lili Fu (付黎黎), Bin Chen (陳斌) and Yuezhen Deng (鄧躍臻) were appointed as independent non-executive directors of the Company and the appointment would take effect from the date of [REDACTED] of the Company.

(c) Five highest paid employees

The five highest paid individuals of the Group included three director or supervisors of the Company for the Track Record Period, details of whose remuneration are set out above. Details of the remuneration for the remaining two highest paid employees for the Track Record Period are as follows:

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Salaries and other benefits	1,122	1,740
Discretionary bonuses (<i>note</i>)	128	187
Retirement benefit scheme contributions	49	104
Share-based payments	3,122	396
	<u>4,421</u>	<u>2,427</u>

Note: Discretionary bonuses are determined based on the duties and performances of the relevant individuals and the operating result of the Group.

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The emoluments of the five highest paid individuals for the years ended December 31, 2021 and 2022 are within the following bands:

	Year ended December 31,	
	2021	2022
	<i>No. of employees</i>	<i>No. of employees</i>
Hong Kong Dollars (“HK\$”)1,000,001 to HK\$1,500,000	–	3
HK\$1,500,001 to HK\$2,000,000	–	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\$5,000,001 to HK\$5,500,000	1	–
HK\$15,000,001 to HK\$15,500,000	1	–
	<u>5</u>	<u>5</u>

During the Track Record Period, no emoluments were paid by the Group to any of the executive director, non-executive directors, independent non-executive directors, or the five highest paid individuals (including directors and employees) as an inducement to join or upon joining the Group or as compensation for loss of office.

13. LOSS PER SHARE

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Loss:		
Loss for the purpose of calculating basic and diluted loss per share	<u>(148,518)</u>	<u>(188,866)</u>
Number of shares (’000):		
Weighted average number of ordinary shares for the purpose of basic loss per share calculation	152,112	172,044
Effect of dilutive potential ordinary shares:		
Ordinary Shares with redemption rights	<u>–</u>	<u>N/A</u>
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share calculation	<u>152,112</u>	<u>172,044</u>
Loss per share		
– Basic	(0.98)	(1.10)
– Diluted	<u>(0.98)</u>	<u>N/A</u>

Certain investors’ shares, which are recorded as redemption liabilities on ordinary shares in note 29, are not treated as outstanding shares and thus are excluded in the calculation of basic loss per share until the redemption right was terminated on August 30, 2021.

The Company was converted to a joint stock company on January 13, 2022, 168,000,000 ordinary shares with par value of RMB1 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered under these shareholders on that day. This capitalization of share capital is applied retrospectively for the purpose of calculating basic loss per share, as adjusted for the capital contributions by the then shareholder.

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Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. Before August 30, 2021, the Company had certain investors’ shares which are ordinary shares with redemption rights, the ordinary shares with redemption rights were not included in the calculation of diluted loss per share, as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the year ended December 31, 2021 is the same as basic loss per share.

No diluted loss per share for 2022 was presented as there was no potential ordinary shares in issue for 2022.

14. DIVIDENDS

No dividend was declared or paid by the Company during the Track Record Period.

15. PROPERTY AND EQUIPMENT

The Group and the Company

	Buildings	Equipment	Furniture and fixture	Motor vehicles	Leasehold improvement	Construction in progress	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
COST							
At January 1, 2021	15,044	65,628	3,154	949	1,760	16,845	103,380
Additions	–	1,397	58	302	–	–	1,757
Disposals	–	(5,520)	(256)	(248)	–	–	(6,024)
At December 31, 2021	15,044	61,505	2,956	1,003	1,760	16,845	99,113
Additions	–	1,193	170	–	–	–	1,363
Disposals	–	(11)	(4)	–	–	–	(15)
At December 31, 2022	15,044	62,687	3,122	1,003	1,760	16,845	100,461
DEPRECIATION							
At January 1, 2021	7,031	35,192	2,866	684	808	–	46,581
Provided for the year	710	5,836	105	165	167	–	6,983
Eliminated on disposals	–	(4,952)	(242)	(238)	–	–	(5,432)
At December 31, 2021	7,741	36,076	2,729	611	975	–	48,132
Provided for the year	710	5,170	96	156	167	–	6,299
Eliminated on disposals	–	(8)	(4)	–	–	–	(12)
At December 31, 2022	8,451	41,238	2,821	767	1,142	–	54,419
CARRYING AMOUNTS							
At December 31, 2021	7,303	25,429	227	392	785	16,845	50,981
At December 31, 2022	6,593	21,449	301	236	618	16,845	46,042

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The above items of property and equipment, other than construction in progress, are depreciated on a straight-line basis, after taking into account of the residual value, over the following period:

Buildings	20 years
Leasehold improvement	Over the shorter of the relevant lease terms or 10 years
Equipment	7 – 10 years
Furniture and fixture	3 – 5 years
Motor vehicles	4 years

As at December 31, 2021 and 2022, the Group has pledged buildings with carrying amounts of RMB7,303,000 and RMB6,593,000 respectively to secure general banking facilities granted to the Group.

16. RIGHT-OF-USE ASSETS

The Group and the Company

	Leasehold lands	Leased properties	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At January 1, 2021	8,709	740	9,449
Addition for the year	–	122	122
Depreciation charge for the year	(211)	(378)	(589)
At December 31, 2021	8,498	484	8,982
Addition for the year	–	125	125
Depreciation charge for the year	(211)	(389)	(600)
At December 31, 2022	<u>8,287</u>	<u>220</u>	<u>8,507</u>
	Year ended December 31,		
	2021	2022	
	<i>RMB'000</i>	<i>RMB'000</i>	
Expenses relating to			
short-term leases	80	181	
Total cash outflow for leases	<u>533</u>	<u>637</u>	

During the Track Record Period, the Group leases various properties for its research and development activities. Lease contracts are entered into for fixed term of 1 year to 4 years. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. In determining the lease term and assessing the length of the non-cancellable period, the Group applies the definition of a contract and determines the period for which the contract is enforceable.

In addition, the Group’s interests in leasehold lands represent prepaid operating lease payments for land located in the PRC and the remaining lease term is 40 years.

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As at December 31, 2021 and 2022, the Group has pledged leasehold lands with carrying amounts of RMB8,498,000 and RMB8,287,000 to secure general banking facilities granted to the Group.

As at December 31, 2021 and 2022, the Group’s lease liabilities of RMB480,000 and RMB169,000 are recognized with related right-of-use assets of RMB484,000 and RMB220,000, respectively. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Except for the leasehold lands, leased assets may not be used as security for borrowing purposes.

The Group regularly entered into short-term leases for equipment and properties. As at 31 December 2021 and 2022, the portfolio of short-term leases is similar to the portfolio of short-term leases to which the short-term lease expense disclosed above.

17. INVESTMENT PROPERTIES

The Group and the Company

RMB’000

COST

At January 1, 2021, December 31, 2021 and 2022	937

DEPRECIATION

At January 1, 2021	311
Provided for the year	45

At December 31, 2021	356
Provided for the year	45

At December 31, 2022	401

CARRYING AMOUNT

At December 31, 2021	581

At December 31, 2022	536

The Group leases out various residential properties under operating leases with fixed rentals receivable monthly.

The Group is not exposed to foreign currency risk as a result of the lease arrangements, as all leases are denominated in the respective functional currencies of group entities. The lease contracts do not contain residual value guarantee and/or lessee’s option to purchase the property at the end of lease term.

The fair value of the Group’s investment properties at December 31, 2021 and 2022 were RMB2,731,000 and RMB2,496,000, respectively. The fair value has been arrived at based on estimates made by the directors of the Company.

In estimating the fair value of the properties, the highest and best use of the properties is their current use.

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Details of the Group’s investment properties and information about the fair value hierarchy as at the end of the reporting period are as follows:

	As at December 31, 2021		As at December 31, 2022	
	Carrying amount	Fair value at Level 2 hierarchy	Carrying amount	Fair value at Level 2 hierarchy
	RMB’000	RMB’000	RMB’000	RMB’000
Residential property units located in Wuhan	581	2,731	536	2,496

The above investment properties are depreciated on a straight-line basis at the following rates per annum:

Investment properties	20 years

As at December 31, 2021 and 2022, the Group has pledged investment properties with carrying amounts of RMB581,000 and RMB536,000 respectively to secure general banking facilities granted to the Group.

18. INVESTMENTS IN SUBSIDIARIES

The Company

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Cost of investments	21,000	21,000

19. INVENTORIES

The Group and the Company

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Materials for research and development project	8,914	10,623

20. PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES

The Group

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Prepayments for research and development services (<i>note</i>)	12,511	19,703
Prepayments for [REDACTED] and [REDACTED]	[REDACTED]	[REDACTED]
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Advance to staff	328	337
Others	279	657
	14,139	27,814

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The Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Prepayments for research and development services (<i>note</i>)	12,511	17,697
Prepayment for [REDACTED] and [REDACTED]	[REDACTED]	[REDACTED]
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Advance to staff	328	337
Others	279	657
	<u>14,139</u>	<u>25,808</u>

Note: Prepayments mainly include upfront fee paid for research and development services for the clinical and non-clinical study of drugs.

21. FINANCIAL ASSETS AT FVTPL

The Group

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Structured deposits (<i>note i</i>)	17,000	32,000
Wealth management products (<i>note ii</i>)	2,500	15,000
	<u>19,500</u>	<u>47,000</u>

The Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Structured deposits (<i>note i</i>)	<u>17,000</u>	<u>32,000</u>

Notes:

- (i) The Group and the Company invested in financial products managed by a financial institution in the PRC. The principal is guaranteed by the relevant financial institutions with expected yield of 1.48% and 1.30% per annum as at December 31, 2021 and 2022 respectively, and the actual yield to be received is uncertain until settlement. The investments have maturity date within one year and are classified as financial assets measured at FVTPL.
- (ii) The Group invested in a wealth management product managed by a financial institution in the PRC with expected rates of return ranging from 2.55% to 3.10% and 2.80% to 4.10% per annum as at December 31, 2021 and 2022 respectively. The investments have maturity date within one year and are classified as financial assets measured at FVTPL.

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22. CASH AND CASH EQUIVALENTS

The Group

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Cash at bank	34,830	153,520
Short-term bank deposits with maturity less than three months	48,255	–
	83,085	153,520

The Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Cash at bank	34,007	152,982
Short-term bank deposits with maturity less than three months	48,255	–
	82,262	152,982

Cash and cash equivalents comprise cash held by the Group and the Company and short-term bank deposits with an original maturity of three months or less and carry interests at prevailing market rates which was from 0.01% to 2.10%, and 0.05% to 0.9% as at December 31, 2021 and 2022 respectively.

23. TRADE AND OTHER PAYABLES

The Group

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Trade payables for research and development expenses	5,380	3,214
Accrued research and development expenses	7,761	15,503
Other payables to government (<i>note i</i>)	3,600	3,600
Accrued staff costs and benefits	2,885	3,456
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Government grants received on behalf of staff (<i>note ii</i>)	275	877
Other tax payables	362	454
Payables for acquisition of property and equipment	117	47
Others	193	77
	22,677	33,555

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The Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Trade payables for research and development expenses	5,380	3,214
Accrued research and development expenses	7,761	12,854
Other payables to government (note i)	3,600	3,600
Accrued staff costs and benefits	2,885	3,456
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Government grants received on behalf of staff (note ii)	275	877
Other tax payables	362	454
Payables for acquisition of property and equipment	117	47
Others	193	77
	22,677	30,906

Notes:

- (i) This amount was asset related government subsidy and attached with conditions that the construction of the buildings should be completed and approved by the respective PRC government authority before December 31, 2016. The Company has not fulfilled the conditions attached to this subsidy at December 31, 2021 and 2022. Therefore, the amount was repayable to the respective PRC government authority on demand.
- (ii) These amounts were government subsidy received on behalf of staff and repayable to staff on demand.

The credit period on purchases of goods/services of the Group and the Company is 0 to 90 days.

The following is an aging analysis of trade payables of the Group and the Company based on the invoice dates at the end of each reporting period:

	At December 31,	
	2021	2022
	RMB'000	RMB'000
0-30 days	2,524	1,795
31-90 days	1,746	628
91-180 days	482	61
181-365 days	169	207
Over 365 days	459	523
	5,380	3,214

Analysis of trade payables and other payables of the Group and the Company denominated in currencies other than the functional currency of relevant group entities is set out below:

	At December 31,	
	2021	2022
	RMB'000	RMB'000
GBP	469	713
HK\$	61	469
US\$	956	5,361
EUR	441	–
CHF	–	754
	1,927	7,297

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24. BANK BORROWINGS

The Group and the Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Secured bank loans (<i>note i</i>)	23,000	45,000
Unsecured bank loans (<i>note ii</i>)	5,000	31,500
	<u>28,000</u>	<u>76,500</u>

	At December 31,	
	2021	2022
	RMB'000	RMB'000
The carrying amounts of the above borrowings are repayable based on scheduled repayment terms:		
Within one year	<u>28,000</u>	<u>76,500</u>

Notes:

- (i) The bank borrowings as at December 31, 2021 were secured, unguaranteed, and carried a fixed-rate interest rate (also being the effective interest rate) of 5.22% per annum. Such bank borrowings were secured by the Group’s property and equipment, right-of-use assets and investment properties with carrying amount of RMB7,303,000, RMB8,498,000, and RMB581,000 respectively as at December 31, 2021. The borrowings were repaid in full in February and March 2022.

The bank borrowings as at December 31, 2022 were secured, unguaranteed, and carried a fixed-rate interest rate (also being the effective interest rate) of 4.35% per annum. Such bank borrowings were secured by the Group’s property and equipment, right-of-use assets and investment properties with carrying amount of RMB6,593,000, RMB8,287,000, and RMB536,000 respectively as at December 31, 2022. The borrowings of RMB18,000,000 were repaid in May 2023, and the remaining RMB27,000,000 will be repayable in June and July 2023.

- (ii) The bank borrowings as at December 31, 2021 were unsecured, guaranteed, and carried a fixed-rate interest rate (also being the effective interest rate) of 5.40% per annum. Such bank borrowing was guaranteed by the Company’s subsidiary of Nanjing Youbodi Biotechnology Co., Ltd* (南京友博迪生物技术有限公司) (“YBD”). The borrowings were repaid in full in June 2022.

The bank borrowings of RMB27,500,000 as at December 31, 2022 were unsecured, unguaranteed, and carried a fixed-rate interest rate (also being the effective interest rate) of 4.80% per annum. The borrowings were repaid in full till April 2023.

The bank borrowings of RMB4,000,000 as at December 31, 2022 were unsecured, unguaranteed, and carried a fixed-rate interest rate (also being the effective interest rate) of 5.10% per annum. The borrowings will be repayable in full in June 2023.

* English name is for identification purpose only.

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The exposure of the Group’s borrowings are as follows:

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Fixed-rate borrowings	28,000	76,500

The ranges of effective interest rates per annum on the Group’s and the Company’s borrowings are as follows:

	At December 31,	
	2021	2022
Effective interest rate:		
Fixed-rate borrowings	5.22%-5.40%	4.35%-5.10%

25. AMOUNT DUE FROM A SUBSIDIARY/AMOUNT DUE TO A RELATED PARTY/A SUBSIDIARY

The Group and the Company

Amount due to a related party

	At December 31,	
	2021	2022
	RMB’000	RMB’000
CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd* (石藥集團中奇製藥技術(石家莊)有限公司) (“CSPC Zhongqi”)	4,659	–

CSPC Zhongqi is a wholly-owned subsidiary of CSPC NBP Pharmaceutical Co., Ltd* (石藥集團恩必普藥業有限公司) (“CSPC”), one of the investors from Series A Shares. The amount was trade nature, unsecured, interest-free and repayable on demand. The maximum outstanding balance during the years ended December 31, 2021 and 2022 were RMB4,659,000 and RMB6,294,000, respectively and the opening balance as at January 1, 2021 was RMB1,501,000.

The aging of amount due to a related party of the Group and the Company, based on the invoice date, are within 30 days as at the end of each reporting period.

The Company

Amount due from a subsidiary

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Wuhan Youwei Biotechnology Co., Ltd* (武漢友微生物技術有限公司) (“YW”) (note i)	–	17,418

* English name is for identification purpose only.

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Amount due to a subsidiary

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Unsecured loan from YBD (<i>note ii</i>)	15,444	–
Other payables to YBD (<i>note iii</i>)	2,572	5,519
	18,016	5,519

Notes:

- (i) The amount was unsecured with the fixed interest rate of 4.50% per annum, and due to be repaid in April 2023. In April 2023, the loan period was further extended to December 2023.
- (ii) The loan was unsecured, with the fixed interest rate of 3.85% per annum, and repaid in full in 2022.
- (iii) The amounts were non-trade in nature, unsecured, interest free and repayable on demand.

26. LEASE LIABILITIES

The Group and the Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Lease liabilities payable:		
Within one year	397	169
Within a period of more than one year but not exceeding two years	83	–
Within a period of more than two years but not exceeding five years	–	–
	480	169
Less: Amount due for settlement with 12 months shown under current liabilities	397	169
Amount due for settlement after 12 months shown under non-current liabilities	83	–

The weighted average incremental borrowing rates applied to lease liabilities range from 5.72% to 5.90% per annum for the Track Record Period.

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27. DEFERRED INCOME

The Group and the Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Subsidies related to research and development activities (<i>note</i>)	1,175	2,975

The movements in deferred income during the Track Record Period are as follows:

	At December 31,	
	2021	2022
	RMB'000	RMB'000
At beginning of the year	924	1,175
Received during the year	1,175	3,816
Recognized in profit for loss during the year	(924)	(2,016)
At end of the year	1,175	2,975

Note: Subsidies are in relation to research and development activities of the Group and the Company. The subsidies can be regarded as fully granted until certain conditions are fulfilled. As at December 31, 2021 and 2022, the relevant conditions have not been fully fulfilled and therefore the government subsidies were classified as deferred income. Such deferred income is categorized as current liabilities because the fulfillment date are reasonably estimated within one year.

28. ADVANCE FROM TRANSFER AGREEMENT

The Group and the Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Upfront fee received from transfer agreement	–	33,761

In July 2022, the Company entered into an agreement with an independent third party (the “Agreement”) to transfer all of the rights and assets relating to one of its drug candidates (the “Transfer”).

The Company is entitled to a fixed upfront fee amounting to USD5,000,000 for the Transfer. According to the Agreement, the upfront fee will be required to refund upon the condition, which is not possible to predict the possibility of occurrence, and the upfront fee was recognised as advance from transfer agreement and classified as current liabilities.

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29. REDEMPTION LIABILITIES ON ORDINARY SHARES

In December 2020, the Company entered into investment agreements with several independent investors (“Series B Investors”), pursuant to which the investors made a total investment of RMB168,700,000 in the Company as consideration for subscription of the Company’s paid-in capital of RMB15,906,000 (“Series B Shares”) with a preference right of the Company (“Series B Financing”). The Company had received all proceeds for Series B Shares by August 2021.

In January 2021, the Company entered into investment agreements with several independent investors (“Series B+ Investors”), pursuant to which the investors made a total investment of RMB20,000,000 in the Company as consideration for subscription of the Company’s paid-in capital of RMB1,886,000 (“Series B+ Shares”) with a preference right of the Company (“Series B+ Financing”). The Company had received all investment funds for Series B+ Shares by March 2021.

In July 2021, the Company entered into investment agreements with several independent investors (“Series B++ Investors”), pursuant to which the investors made a total investment of RMB73,500,000 in the Company as consideration for subscription of the Company’s paid-in capital of RMB5,851,000 (“Series B++ Shares”) with a preference right of the Company (“Series B++ Financing”). The Company had received all investment funds for Series B++ Shares by August 2021.

The key terms of the Series B, Series B+ and Series B++ Financing are summarized as follows:

Redemption rights

One of Series B Investors (“Investor B-I”) and Series B++ Investors were entitled to the redemption right, upon the occurrence of certain events, including: (i) [REDACTED] cannot be submitted and accepted on or before December 31, 2022, or (ii) [REDACTED] cannot be completed on or before June 30, 2023. If [REDACTED] fails to be submitted and accepted on or before December 31, 2022, Mr. Yuan Qian, Mr. Zhou Hongfeng and Mr. Pengfei Zhou (“founders”) and Wuhan Caizhi Management Partnership (Limited Partnership) (“Caizhi”) will be obligated to repurchase the shares from Investor B-I and Series B++ Investors at the original investment plus a yield at 10% per annum and minus any paid dividends. If [REDACTED] fails to be completed on or before June 30, 2023, Mr. Pengfei Zhou, one of the founders, and Caizhi will be obligated to repurchase the shares from Investor B-I and Series B++ Investors at the amount of the original investment from the investors plus a yield at 10% per annum and minus any paid dividends, and limited to the higher of the fair value and net book value of equity interests of the Company held by Mr. Pengfei Zhou and Caizhi. The Company was jointly liable for the redemption obligations, which was recognized as the financial liabilities at amortized cost.

The remaining Series B Investors and Series B+ Investors were entitled to the redemption right, upon the occurrence of the event that [REDACTED] cannot be completed on or before June 30, 2023. If [REDACTED] fails to be completed on or before June 30, 2023, Mr. Pengfei Zhou, one of the founders, and Caizhi will be obligated to repurchase the shares from the remaining Series B Investors and Series B+ Investors at the amount of the original investment from the investors plus a yield at 10% per annum and minus any paid dividends, and limited to the higher of the fair value and net book value of the equity interests of the Company held by Mr. Pengfei Zhou and Caizhi. The Company was jointly liable for the redemption obligations, which was recognized as the financial liabilities at amortized cost.

The redemption rights aforementioned hereinabove was terminated on August 30, 2021. Accordingly, the amounts of the financial liabilities at amortized cost were derecognized and credited to other reserve.

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Presentation and classification

The redemption obligations give rise to financial liabilities, which are measured at present value of redemption amount. The movements of redemption liabilities during the Track Record Period are set out below.

	Series B	Series B+	Series B++	Interest payable	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
As at January 1, 2021	105,047	–	–	–	105,047
Recognition of liabilities on Series B Shares	47,461	–	–	–	47,461
Recognition of liabilities on Series B+ Shares	–	17,736	–	–	17,736
Recognition of liabilities on Series B++ Shares	–	–	68,845	–	68,845
Interest charge	–	–	–	13,722	13,722
Termination of redemption liabilities on Series B, B+ and B++ Shares	(152,508)	(17,736)	(68,845)	(13,722)	(252,811)
As at December 31, 2021	–	–	–	–	–

The Group used the effective interest method to determine the amortized cost of ordinary shares with redemption liabilities which takes into account of the repurchase price on the earliest redemption date of each series and maturity dates. The directors of the Company estimated the effective interest rate based on the yield of the China Corporate Bonds with a similar maturity life of the ordinary shares with redemption obligations.

30. PAID-IN CAPITAL/SHARE CAPITAL

As disclosed in note 1, the Company converted into a joint stock company on January 13, 2022. The balance as at January 1, 2021 and December 31, 2021 represented the paid-in capital of the Company prior to the conversion to a joint stock company. Share capital as at December 31, 2022 represented the issued share capital of the Company.

Paid-in capital

Issued and paid

	Paid-in capital
	RMB'000
At January 1, 2021	156,392
Issue of Series B Shares-second and third tranche (<i>note i</i>)	943
Issue of Series B+ Shares (<i>note ii</i>)	1,886
Issue of Series B++ Shares (<i>note iii</i>)	5,851
At December 31, 2021	165,072
Conversion into a joint stock company (<i>note iv</i>)	(165,072)
At December 31, 2022	–

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Share capital

	Number of shares	Nominal value of shares
		<i>RMB’000</i>
Authorized and issued		
As at January 1, 2021, December 31, 2021	–	–
Issue of ordinary shares upon conversion into a joint stock company (<i>note iv</i>)	168,000,000	168,000
Issue of shares (<i>note v</i>)	14,000,000	14,000
As at December 31, 2022	182,000,000	182,000

Notes:

- (i) In January 2021, the Company received second tranche of RMB20,000,000 from Series B Investors, among which RMB943,000 was credited to the Company’s paid-in capital and the remaining balance was credited as capital reserve. In August 2021, the Company received third tranche of RMB31,710,000 from Series B Investors, and the amount was credited as capital reserve.
- (ii) In January 2021, the Company completed Series B+ Financing with RMB20,000,000 invested into the Company, among which RMB1,886,000 was credited to the Company’s paid-in capital and the remaining balance was credited as capital reserve.
- (iii) In July 2021, the Company completed Series B++ Financing with RMB73,500,000 invested into the Company, among which RMB5,851,000 was credited to the Company’s paid-in capital and the remaining balance was credited as capital reserve.
- (iv) On January 13, 2022, 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 date of August 31, 2021, including paid-in capital, reserves and accumulated losses, amounting to approximately RMB175,384,000 were converted into approximately 168,000,000 ordinary shares at RMB1.00 each. The excess of net assets converted over nominal value of the ordinary shares was credited to the Company’s share premium.
- (v) In October 2022, the Company issued 14,000,000 ordinary shares at the consideration of RMB200,000,000 to investors. RMB14,000,000 was credited to the Company’s share capital and the remaining balance was credited as share premium.

31. RESERVES

The Group

The amounts of the Group’s reserves and the movement therein are presented in the consolidated statements of change in equity on pages I-[8] of the Historical Financial Information.

(i) Capital reserve

The capital reserve of the Group represents the premium of paid-in capital contributed by the equity holders of the Company.

(ii) Other reserves

Other reserve of the Group represents recognition and termination of redemption liabilities on ordinary shares as disclosed in note 29.

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(iii) *Share-based payment reserve*

Share-based payment reserve of the Group represents share-based compensation reserve due to equity-settled share awards.

The Company

	Capital reserve	Share premium	Other reserve	Share-based payment reserve	Accumulated losses	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At January 1, 2021	293,198	–	(105,047)	48,632	(423,833)	(187,050)
Loss and total comprehensive expenses for the year	–	–	–	–	(148,942)	(148,942)
Contribution from Series A Investors	4,700	–	–	–	–	4,700
Debt waived by Series A Investors (<i>note 33</i>)	14,100	–	–	–	–	14,100
Issue of Series B Shares-second and third tranche	50,767	–	–	–	–	50,767
Issue of Series B+ Shares	18,114	–	–	–	–	18,114
Issue of Series B++ Shares	67,649	–	–	–	–	67,649
Recognition of liabilities on Series B, B+, and B++ Shares (<i>note 29</i>)	–	–	(134,042)	–	–	(134,042)
Termination of redemption liabilities on Series B, B+, and B++ Shares (<i>note 29</i>)	–	–	252,811	–	–	252,811
Recognition of equity-settled share-based payments (<i>note 32</i>)	–	–	–	39,646	–	39,646
At December 31, 2021	448,528	–	13,722	88,278	(572,775)	(22,247)
Issue of shares	–	186,000	–	–	–	186,000
Loss and total comprehensive expenses for the year	–	–	–	–	(170,964)	(170,964)
Recognition of equity-settled share-based payments	–	–	–	1,584	–	1,584
Conversion into a joint stock company	(448,528)	7,384	(13,722)	(88,278)	540,216	(2,928)
At December 31, 2022	–	193,384	–	1,584	(203,523)	(8,555)

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32. SHARE-BASED PAYMENT TRANSACTIONS

Equity incentive plan

The Company adopted equity incentive plan (“ESOP Plan”) in order to provide incentives to employees and directors to promote the success of the business of the Group.

Under the ESOP Plan, the founders of the Company may grant share options to eligible employees and directors. The maximum number of shares which may be issued pursuant to all awards granted under the ESOP Plan was 16,500,000 shares, assuming the ESOP Plan shares have been fully issued.

The vesting commencement date (“Vesting Commencement Date”) of the options granted under the ESOP Plan is one year after date of grant and the options granted shall vest in below schedule: (i) 1/4th of the share options to vest on the Vesting Commencement Date; (ii) the remaining share options to vest in a series of thirty-six (36) successive equal monthly installments starting from the Vesting Commencement Date. All the options will expire in 10 years after date of grant.

To implement the ESOP plan, the founders of the Company established an employee stock ownership platform, namely Caizhi in August 2015, to hold the Company’s paid-in capital of RMB16,500,000, which was transferred from the founders. Upon exercise of the options, eligible employees and directors shall subscribe for partnership interest of Caizhi at a consideration price ranges from RMB0.8 to RMB6.36 for RMB1 registered capital and indirectly hold the equity interests of the Company.

In August 2021, the Company terminated the ESOP Plan and all the share options granted. The share options which account for RMB3,285,000 of the Company’s paid-in capital, have been exercised in Caizhi before termination.

Restricted shares plan

As a replacement for the ESOP Plan, the Company has formulated RS scheme (“Caizhi I RS Scheme”). To implement Caizhi I RS Scheme, another two employee stock ownership platforms, namely Nanjing Huiyou Jucai Enterprise Management Partnership (Limited Partnership) (“Huiyou Jucai”) and Nanjing Huiyou Juzhi Enterprise Management Partnership (Limited Partnership) (“Huiyou Juzhi”) were established in August 2021. On the date of establishment, Caizhi transferred the Company’s paid-in capital of RMB8,375,000 and RMB4,840,000 to Huiyou Jucai and Huiyou Juzhi respectively, and the Company’s paid-in capital of RMB3,285,000 were retained in Caizhi.

Under the Caizhi I RS Scheme, eligible employees and directors shall subscribe for partnership interest of Huiyou Jucai and Huiyou Juzhi at a consideration price ranges from RMB1.58 to RMB6.36 for RMB1 registered capital and indirectly hold the incentive shares of the Company.

On the same date of terminating all the options granted under ESOP Plan, the Company has signed Employee Shareholding Confirmation Letter with those employees and directors who has been granted share options under ESOP Plan to grant same number of RS corresponding to the number of original options no matter whether the original options have been vested or not. In the meantime, the Company also grant additional RS to part of those employees who have been granted share options in the ESOP plan and other key employees who make contribution to the development of the Company.

The RS issued under Caizhi I RS Scheme have been vested upon issuance in August 2021.

In the view of Directors of the Company, the Caizhi I RS Scheme was a replacement of ESOP Plan and therefore was accounted for as modification in accordance with *IFRS 2 Share-based Payment*. The amount of RMB11,554,000 was recognized immediately in the consolidated statements of profit or loss and other comprehensive income due to the acceleration of vesting of the share options under ESOP plan. The amount of RMB4,135,000 was recognized in the consolidated statements of profit or loss and other comprehensive income due to the grant of additional RS under Caizhi I RS Scheme.

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Set out below are details of the movements of the equity-settled share-based transactions during the Track Record Period:

	At January 1, 2021	Granted during the year	Lapsed during the year	Forfeited during the year	Modified during the year	Exercised during the year	At December 31, 2021	Granted during the year	Lapsed during the year	Forfeited during the year	Modified during the year	Exercised during the year	At December 31, 2022
Options under ESOP Plan													
Directors	4,144,250	250,000	-	-	(4,394,250)	-	-	-	-	-	-	-	-
Employees	3,879,317	3,720,000	211,458	568,542	(6,819,317)	-	-	-	-	-	-	-	-
	<u>8,023,567</u>	<u>3,970,000</u>	<u>211,458</u>	<u>568,542</u>	<u>(11,213,567)</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Weighted average exercise price of Options (RMB)	2.97	6.36	6.36	6.36	3.94	-	-	-	-	-	-	-	-
Exercisable (Options under ESOP Plan)													
Directors							-						-
Employees							-						-
							<u>-</u>						<u>-</u>
RS under Caizhi I RS Scheme													
Directors	-	-	-	-	4,394,250	4,394,250	-	-	-	-	-	-	-
Employees	-	2,001,325	-	-	6,819,317	8,820,642	-	200,000	-	-	-	(200,000)	-
	<u>-</u>	<u>2,001,325</u>	<u>-</u>	<u>-</u>	<u>11,213,567</u>	<u>13,214,892</u>	<u>-</u>	<u>200,000</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(200,000)</u>	<u>-</u>
Weighted average exercise price of RS (RMB)	-	6.36	-	-	3.94	4.32	-	6.36	-	-	-	6.36	-

Fair value of share options granted

The Group used back-solve method to determine the underlying equity fair value of the Company. Binomial Option Pricing Model was used to determine the fair value of share options at the date of grant under ESOP Plan. The fair value of share options was determined to be in the range from RMB2.99 to RMB3.93 during the Track Record Period, by referring to the equity fair value of the Company and the exercise prices of the share options of RMB6.36. The foresaid fair value of the share options at date of grant was valued by directors of the Company with reference to valuation reports carried out by AVISTA Valuation Advisory Limited (“AVISTA”), an independent qualified valuer. The address of AVISTA is Suites 2401-06, 24/F, Everbright Centre, No 108 Gloucester Road, Wan Chai, Hong Kong. Key assumptions into the model for share options were as follows:

	August 2018	December 2018	July 2019	August 2020	June 2021
Grant date fair value of the Company’s shares	RMB5.95	RMB6.09	RMB6.23	RMB6.34	RMB6.75
Exercise price	RMB6.36	RMB6.36	RMB6.36	RMB6.36	RMB6.36
Expected volatility	53.34%	50.15%	49.75%	50.57%	51.41%
Expected life	10 years	10 years	10 years	10 years	10 years
Risk-free rate	3.55%	3.17%	3.17%	3.03%	3.04%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%

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The directors of the Company estimated the risk-free interest rate based on the yield of the China Corporate Bonds with a maturity life close to the option life of the share options. Volatility was estimated at grant date based on average of historical volatilities of the comparable companies with length commensurable to the time to maturity of the share options. Expected dividend yield is based on management estimation at the grant date.

During year ended December 31, 2021 and 2022, the Group has recognized share-based payment expenses of RMB14,790,000 and Nil, respectively, related to the ESOP Plan.

Fair value of RS granted under Caizhi I RS Scheme

The Group used back-solve method to determine the underlying equity fair value of the Company. The fair value of RS at date of grant was determined to be in the range from 2.07 to 7.93 by taking into account of the fair value of the equity of the Company ranged from RMB8.43 to RMB14.29 per share and the purchase price of RS was RMB6.36. The foresaid fair value of RS at date of grant was valued by directors of the Company with reference to valuation reports carried out by AVISTA.

During year ended December 31, 2021 and 2022, the Group has recognized share-based payment expenses of RMB4,135,000 and RMB1,584,000, respectively, related to the Caizhi I RS scheme.

Restricted shares plan under Caizhi II Enterprise Management

In August 2021, Mr. Yuan Qian and Mr. Zhou Hongfeng, two of the founders, and Series A investors of the Company established an employee stock ownership platform, namely Nanjing Caizhi No. 2 Enterprise Management Partnership (Limited Partnership) (“Caizhi II”) to hold the Company’s paid-in capital of RMB11,418,000, to implement RS scheme (“Caizhi II RS Scheme”).

Under the Caizhi II RS Scheme, eligible employees and directors shall subscribe for partnership interest of Caizhi II at a consideration of RMB6.364 for RMB1 registered capital and indirectly hold the incentive shares of the Company.

Details of the restricted shares issued under the Caizhi II RS Scheme are as follows:

<u>Grant date</u>	<u>Amount of registered capital</u>	<u>Grantee</u>	<u>Vesting schedule defined in contract term</u>
	<i>RMB'000</i>		
August 20, 2021	11,418	Directors, employees	100% on grant date

All restricted shares issued under Caizhi II RS Scheme have been vested upon issuance in August 2021.

Fair value of RS granted under Caizhi II RS Scheme

The Group used back-solve method to determine the underlying equity fair value of the Company. Monte Carlo simulation model was used to determine the fair value of RS at the date of grant under Caizhi II RS Scheme. The fair value of RS was determined to be RMB1.81, by referring to the fair value of the equity of the Company amounting to RMB8.43 per share and the purchase price of RS of RMB6.36. The foresaid fair value of RS at date of grant was valued by directors of the Company with reference to valuation reports carried out by AVISTA.

During year ended December 31, 2021 and 2022, the Group has recognized share-based payment expenses of RMB20,721,000 and Nil, respectively, related to the Caizhi II RS scheme.

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33. RELATED PARTY TRANSACTIONS

The Group has the following transactions and balances with the related parties during the Track Record Period.

(a) Related party transactions

Interest expenses arising from borrowings from related parties:

	Year ended December 31,	
	2021	2022
	RMB'000	RMB'000
CSPC (<i>note i</i>)	396	–
Shijiazhuang Shidai Weiye Cultural Development Co., Ltd* (“石家莊市時代偉業文化發展有限公司”) (<i>SDWY</i>) <i>note (ii)</i>	93	–
Total	489	–

Notes:

- (i) The interest expenses are related to secured loan from CSPC with principal amount of RMB71,070,000 and unsecured loan from CSPC with principal amount of RMB9,118,000.

The secured loan from CSPC carried fixed interest rate of 8% per annum, and repayable on December 31, 2022. Pursuant to investment agreements with Series B Investors (as defined in note 29), the loan should be repaid to CSPC within 30 days upon receipt of proceeds from issuance of Series B Shares (as defined in note 29). The amount of principal and interest of the loan were fully repaid in January 2021. The interest expenses for the year ended December 31, 2021 was RMB281,000.

The unsecured loan from CSPC carried fixed interest rate of 8% per annum. According to the loan agreement, the amount of principal and interest of the loan should be repaid to CSPC if proceeds from issuance of Series B Shares (as defined in note 29) would be received by the Company before December 31, 2020. The principal amount of the loan were waived by CSPC in March 2021, and the interest of the loan were fully settled in March 2021. The interest expenses for the year ended December 31, 2021 was RMB115,000.

- (ii) The interest expenses are related to unsecured loan from SDWY with principal amount of RMB4,982,000. The loan carried fixed interest rate of 8% per annum. According to the loan agreement, the amount of principal and interest of the loan should be repaid to SDWY if proceeds from issuance of Series B Shares (as defined in note 29) would be received by the Company before December 31, 2020. The principal amount of the loan were waived by SDWY in March 2021, and the interest of the loan were fully settled in March 2021. The interest expenses for the year ended December 31, 2021 was RMB93,000.

Purchase of research and development service from a related party:

	Year ended December 31,	
	2021	2022
	RMB'000	RMB'000
CSPC Zhongqi	4,045	2,245

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(b) Related party balances

Details of the outstanding balances with related parties are set out in note 25.

(c) Compensation of key management personnel

The remuneration of the directors of the Company and other members of key management of the Group during the Track Record Period were as follows:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Salaries and other benefits	5,476	6,249
Discretionary bonuses	557	564
Retirement benefit scheme contributions	169	291
Share-based payment	19,373	396
	<u>25,575</u>	<u>7,500</u>

34. CAPITAL COMMITMENT

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Capital expenditure contracted for but not provided in the Historical financial Information:		
– Property and equipment	<u>257</u>	<u>1,116</u>

35. CAPITAL RISK MANAGEMENT

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximising the return to investors through the optimisation of the debt and equity balance. The Group’s overall strategy remains unchanged throughout the Track Record Period.

The capital structure of the Group consists of net debts, which includes bank borrowings, amounts due to shareholders, lease liabilities and redemption liabilities on ordinary shares, net of cash and cash equivalents and equity attributable to owners of the Company, comprising paid-in capital, share capital and reserves.

The management of the Group reviews the capital structure regularly. As part of this review, the management of the Group considers the cost of capital and the risks associated with each class of capital. Based on recommendations of the management of the Group, the Group will balance its overall capital structure through the new share issues as well as the issue of new debt.

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36. FINANCIAL INSTRUMENTS

(a) Categories of financial instruments

The Group

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Financial assets		
Amortized cost (including cash and cash equivalents)	83,364	154,177
Financial assets at FVTPL	19,500	47,000
	<u>102,864</u>	<u>201,177</u>
Financial liabilities		
Amortized cost	<u>52,089</u>	<u>106,145</u>

The Company

	At December 31,	
	2021	2022
	RMB'000	RMB'000
Financial assets		
Amortized cost (including cash and cash equivalents)	82,541	171,057
Financial assets at FVTPL	17,000	32,000
	<u>99,541</u>	<u>203,057</u>
Financial liabilities		
Amortized cost	<u>70,105</u>	<u>109,015</u>

(b) Financial risk management objectives and policies

The Group’s major financial assets and liabilities include deposits and other receivables, cash and cash equivalents, trade and other payables, bank borrowings, amount due to a related party and lease liabilities. The Company’s major financial assets and liabilities include deposits and other receivables, amount due from a subsidiary, cash and cash equivalents, trade and other payables, bank borrowings, amount due to a subsidiary, amount due to a related party and lease liabilities. Details of these financial assets and liabilities are disclosed in respective notes.

The risks associated with these financial assets and liabilities include market risks (currency risk, interest rate risk and other price risk), credit risk and liquidity risk. The policies on how to mitigate these risks are set out below. The management manages and monitors these exposures to ensure appropriate measures are implemented on a timely and effective manner.

Market risk

The Group’s and the Company’s activities expose it primarily to currency risk, interest rate risk and other price risk. There has been no change in the Group’s and the Company’s exposure to these risks or the manner in which it manages and measures the risks.

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(i) *Currency risk*

Certain financial liabilities are denominated in foreign currency of respective group entities which are exposed to foreign currency risk. The Group currently does not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

The carrying amounts of the Group’s and the Company’s foreign currency denominated monetary assets at the end of each reporting period are mainly as follows:

The Group and the Company

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Liabilities		
GBP	469	713
HK\$	61	469
US\$	956	5,361
EUR	441	–
CHF	–	754
	1,927	7,297

Sensitivity analysis

The following table details the Group’s and the Company’s sensitivity to a 5% increase and decrease in RMB against GBP/HK\$/US\$/EUR/CHF, the foreign currency with which the Group and the Company may have a material exposure. 5% represents management’s assessment of the reasonably possible change in foreign exchange rate. The sensitivity analysis uses outstanding foreign currency denominated monetary items as a base and adjusts their translation at the end of the reporting period for a 5% change in foreign currency rate. A positive number below indicates a decrease in loss where RMB strengthens 5% against GBP/HK\$/US\$/EUR/CHF. For a 5% weakening of RMB against GBP/HK\$/US\$/EUR/CHF, there would be an equal and opposite impact on loss for the year.

	At December 31,	
	2021	2022
	RMB’000	RMB’000
Impact on profit or loss		
The Group and the Company		
GBP	23	36
HK\$	3	23
US\$	48	268
EUR	22	–
CHF	–	38
	96	365

(ii) *Interest rate risk*

The Group and the Company are primarily exposed to fair value interest rate risk in relation to bank borrowings, amounts due to shareholders, lease liabilities and cash flow interest rate risk in relation to bank balances. The Group currently does not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

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The Group considers that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant because the current market interest rates are relatively low and stable, therefore no sensitivity analysis on such risk has been prepared.

Credit risk

The Group’s maximum exposure to credit risk which will cause a financial loss to the Group is arising from the amount of each class of financial assets (including deposits and other receivables, amount due from a subsidiary, and cash and cash equivalents) as disclosed in the consolidated statements of financial position. The Group does not hold any collateral or other credit enhancements to cover its credit risks associated with its financial assets.

For deposits and other receivables, the Group has applied 12m ECL in IFRS 9 to measure the loss allowance. The ECL on other receivables are assessed individually based on historical settlement records and past default experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current as well as the forecast direction of conditions at the end of each reporting period. No loss allowance was made for deposits and other receivables at the end of each reporting period, as the management considered the ECL provision of deposits and other receivables is insignificant.

For amount due from a subsidiary, the Group has applied 12m ECL to measure the loss allowance. In assessing the probability of defaults of amount due from a subsidiary, the management has taken into account the financial position of the counterparty as well as forward looking information that is available without undue cost or effort. No loss allowance was made for amount due from a subsidiary at the end of each reporting period, as the management considered the ECL provision of amount due from a subsidiary is insignificant.

The credit risk on cash and cash equivalents are limited because the counterparties are reputable financial institutions. The management are of the opinion that the average loss rate is insignificant and no impairment was provided at the end of each reporting period.

Liquidity risk

In the management of the liquidity risk, the Group and the Company monitors and maintains a level of cash and cash equivalents deemed adequate by the management to finance the Group’s and the Company’s operations and mitigate the effects of fluctuations in cash flows. The Group monitors the utilization of bank borrowings and relies on issuance of Investors’ Shares and ordinary shares as a significant source of liquidity. The directors of the Company are satisfied that the Group will have sufficient financial resource to meet its financial obligation as they fall due and to sustain its operations for the foreseeable future.

The following table details the Group’s and the Company’s remaining contractual maturity for its financial liabilities and lease liabilities. The table has been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Group can be required to pay. The table includes both interest and principal cash flows.

	Weighted average effective interest rate	Within 1 year and on demand	1 to 2 years	2 to 5 years	Total	Carrying amount
	%	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
The Group						
At December 31, 2021						
Trade and other payables	–	19,430	–	–	19,430	19,430
Amount due to a related party	–	4,659	–	–	4,659	4,659
Bank borrowings	5.31	28,303	–	–	28,303	28,000
Lease liabilities	5.81	416	84	–	500	480
		<u>52,808</u>	<u>84</u>	<u>–</u>	<u>52,892</u>	<u>52,569</u>

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	Weighted average effective interest rate	Within 1 year and on demand	1 to 2 years	2 to 5 years	Total	Carrying amount
	%	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
The Group						
At December 31, 2022						
Trade and other payables	–	29,645	–	–	29,645	29,645
Bank borrowings	4.75	78,701	–	–	78,701	76,500
Lease liabilities	5.81	173	–	–	173	169
		108,519	–	–	108,519	106,314

	Weighted average effective interest rate	Within 1 year and on demand	1 to 2 years	2 to 5 years	Total	Carrying amount
	%	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
The Company						
At December 31, 2021						
Trade and other payables	–	19,430	–	–	19,430	19,430
Bank borrowings	5.31	28,303	–	–	28,303	28,000
Amount due to a subsidiary	3.85	18,474	–	–	18,474	18,016
Amount due to a related party	–	4,659	–	–	4,659	4,659
Lease liabilities	5.81	416	84	–	500	480
		71,282	84	–	71,366	70,585

	Weighted average effective interest rate	Within 1 year and on demand	1 to 2 years	2 to 5 years	Total	Carrying amount
	%	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
The Company						
At December 31, 2022						
Trade and other payables	–	26,996	–	–	26,996	26,996
Bank borrowings	4.75	78,701	–	–	78,701	76,500
Amount due to a subsidiary	–	5,519	–	–	5,519	5,519
Lease liabilities	5.81	173	–	–	173	169
		111,389	–	–	111,389	109,184

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(c) Fair value measurements of financial instruments

This note provides information about how the Group determines fair values of various financial assets and financial liabilities.

(i) Fair value measurements and valuation processes

Some of the Group’s and the Company’s financial instruments are measured at fair value for financial reporting purposes. The directors of the Company are responsible to determine the appropriate valuation techniques and inputs for fair value measurements.

In estimating the fair value, the Group and the Company use market-observable data to the extent it is available. Where Level 1 inputs are not available, the Group and the Company engage third party qualified valuers to perform the valuation and works closely with the qualified valuer to establish the appropriate valuation techniques and inputs to the model.

(ii) Fair value of the Group’s financial assets and financial liabilities that are measured at fair value on a recurring basis

Some of the Group’s and the Company’s financial assets are measured at fair value at the end of each reporting period. The following table gives information about how the fair values of these financial assets are determined (in particular, the valuation technique(s) and inputs used).

The Group

	Fair value as at December 31, 2021	Fair value as at December 31, 2022	Fair value hierarchy	Valuation technique(s) and key inputs	Significant Unobservable inputs	Relationship of unobservable inputs to fair value
	<i>RMB’000</i>	<i>RMB’000</i>				
Financial assets at FVTPL	19,500	47,000	Level 2	Income approach- the discounted cash flow method was used to estimate the return from underlying assets.	N/A	N/A

The Company

	Fair value as at December 31, 2021	Fair value as at December 31, 2022	Fair value hierarchy	Valuation technique(s) and key inputs	Significant Unobservable inputs	Relationship of unobservable inputs to fair value
	<i>RMB’000</i>	<i>RMB’000</i>				
Financial assets at FVTPL	17,000	32,000	Level 2	Income approach- the discounted cash flow method was used to estimate the return from underlying assets.	N/A	N/A

There were no transfers between level 1 and level 2 during the Track Record Period.

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(iii) Fair value of financial assets and financial liabilities that are not measured at fair value

The directors of the Company consider that the carrying amount of the Group’s and the Company’s financial assets and financial liabilities recorded at amortized cost in the Historical Financial Information approximate to their fair values. Such fair values have been determined in accordance with generally accepted pricing models based on a discounted cash flow analysis.

37. RETIREMENT BENEFIT PLANS

The employees of the Group entities in the PRC are members of the state-sponsored retirement benefit scheme organized by the relevant local government authority in the PRC. The PRC entities are required to contribute, based on a certain percentage of the payroll costs of their employees, to the retirement benefit scheme and have no further obligations for the actual payment of pensions or post-retirement benefits beyond the annual contributions. The total amount provided by the Group to the scheme in the PRC and charged to profit or loss are RMB2,240,000, and RMB3,440,000 for the year ended December 31, 2021 and 2022, respectively.

38. PARTICULARS OF SUBSIDIARIES

As at December 31, 2021 and 2022 and the date of this report, the Group’s subsidiaries are as follows:

Name of subsidiaries	Place/country and date of establishment/ incorporation	Issued and fully paid-in/registered capital	Equity interest attributable to the Company			Principal activities
			December 31, 2021	December 31, 2022	Date of the report	
Shijiazhuang Shiyong Biotechnology Co., Ltd.* (石家莊石友生物技術有限公司) (“SY”)	Shijiazhuang April 21, 2020	Nil	100%	100%	[100%]	Research and development
YBD	Nanjing December 29, 2020	RMB20,000,000 (note i)	100%	100%	[100%]	Research and development
YW	Wuhan March 22, 2021	RMB1,000,000 (note ii)	100%	100%	[100%]	Research and development

Notes:

- (i) The registered capital was fully paid by the Company on January 29, 2021.
- (ii) The registered capital was fully paid by the Company on August 23, 2021.

All of the subsidiaries adopted December 31 as financial year end.

No statutory financial statements have been prepared for SY, YBD and YW since the date of establishment.

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39. RECONCILIATION OF LIABILITIES ARISING FROM FINANCING ACTIVITIES

The table below details changes in the Group’s liabilities arising from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are those for which cash flows were, or future cash flows will be, classified in the Group’s consolidated statement of cash flows as cash flows from financing activities.

	Bank borrowings	Amounts due to shareholders	Lease liabilities	Redemption liabilities on ordinary shares	Accrued/ Prepaid [REDACTED]	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At January 1, 2021	21,000	87,918	769	105,047	[REDACTED]	214,734
Financing cash flows	6,281	(74,307)	(453)	–	[REDACTED]	(68,876)
Non-Cash changes:						
[REDACTED] incurred	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Debt waived by Series A Investors	–	(14,100)	–	–	[REDACTED]	(14,100)
Recognition of redemption liabilities	–	–	–	134,042	[REDACTED]	134,042
Derecognition of financial liabilities	–	–	–	(252,811)	[REDACTED]	(252,811)
New leases entered	–	–	122	–	[REDACTED]	122
Finance costs	719	489	42	13,722	[REDACTED]	14,972
At December 31, 2021	28,000	–	480	–	[REDACTED]	28,973
Financing cash flows	46,052	–	(456)	–	[REDACTED]	41,334
Non-Cash changes						
[REDACTED] incurred	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
New leases entered	–	–	125	–	[REDACTED]	125
Finance costs	2,448	–	20	–	[REDACTED]	2,468
At December 31, 2022	76,500	–	169	–	[REDACTED]	78,570

40. MAJOR NON-CASH TRANSACTIONS

During the Track Record Period, the Group granted share options/RS to certain employees. Further details are given in note 32.

In March 2021, the borrowings from CSPC and SDWY were waived. Further details are given in note 33.

41. SUBSEQUENT EVENTS

There are no material subsequent events undertaken by the Company or by the Group after December 31, 2022 and up to the date of this report.

42. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements of the Group, the Company or any of its subsidiaries have been prepared in respect of any period subsequent to December 31, 2022 and up to the date of this report.

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX III

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TAXATION OF SECURITY HOLDERS

Income tax and capital gains tax of holders of the H shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of the H shares are resident or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current laws and practices, and has not taken in to account the expected change or amendment to the relevant laws or policies and does not constitute any opinion or advice. The discussion does not deal with all possible tax consequences relating to an investment in the H shares, nor does it take into account the specific circumstances of any particular investor. Accordingly, you should consult your own tax advisor regarding the tax consequences of an investment in the H shares. The discussion is based upon laws and relevant interpretations in effect as of the Latest Practicable Date, all of which are subject to change or adjustment and may have retrospective effect.

This discussion does not address any aspects of PRC or Hong Kong taxation other than income tax, capital gains tax and profits tax, sales tax, value-added tax, stamp duty and estate duty. Prospective investors are urged to consult their financial advisors regarding the PRC, Hong Kong and other tax consequences of owning and disposing of the H shares.

TAXATION IN THE PRC

Tax on Dividends

Individual Investors

According to the Individual Income Tax Law of the People’s Republic of China (《中華人民共和國個人所得稅法》) the “**Individual Income Tax Law**” or the “**IIT Law**”) amended by the SCNPC on August 31, 2018 and effective on January 1, 2019, and the Implementation Rules of the Individual Income Tax Law of the People’s Republic of China (《中華人民共和國個人所得稅法實施條例》) amended by the State Council on December 18, 2018 and effective on January 1, 2019, dividends paid by PRC companies to individual investors are ordinarily subject to a withholding income tax levied at a flat rate of 20%. Meanwhile, according to the Notice on Issues Concerning Differentiated Individual Income Tax Policies on Dividends and Bonus of Listed Companies (《關於上市公司股息紅利差別化個人所得稅政策有關問題的通知》) issued by the Ministry of Finance, the State Administration of Taxation and the CSRC on September 7, 2015 and effective on September 8, 2015, where an individual holds the shares of a listed company obtained from the public offering for more than one year and transfers the stock of the listed company on the stock market, the dividend and bonus income shall be temporarily exempted from individual income tax. Where an individual acquires shares of a listed company from the public offering and transfers the stock of the listed company on the stock market, if the holding period is within one month (inclusive), the dividend income shall be included in the taxable income in full; if the holding period is more than one month but less than one year (inclusive), the dividend income shall be included in the taxable income at the rate of 50%; the aforesaid income shall be subject to individual income tax at a uniform rate of 20%.

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TAXATION AND FOREIGN EXCHANGE

Pursuant to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (the “**Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income**”) signed by the Mainland of China and the Hong Kong Special Administrative Region on August 21, 2006, the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of the equity interests in a PRC company and the Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (《國家稅務總局關於<內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排>第五議定書》) (the “**Fifth Protocol**”) issued by The State Administration of Taxation and effective on December 6, 2019 provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

Enterprise Investors

Pursuant to the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》) (the “**EIT Law**”) amended by the SCNPC and effective on December 29, 2018, and the Implementation Rules of the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法實施條例》) (the “**Implementation Rules of the EIT Law**”) amended by the State Council and effective on April 23, 2019, a non-resident enterprise is subject to a 10% enterprise income tax on PRC-sourced income, including dividends paid by a PRC resident enterprise that issues and lists shares in Hong Kong, if such non-resident enterprise does not have an establishment or place of business in the PRC or has an establishment or place of business in the PRC but the PRC-sourced income is not actually connected with such establishment or place of business in the PRC. The aforesaid income tax payable by non-resident enterprises shall be withheld at source, and the payer shall be the withholding agent, and the tax shall be withheld by the withholding agent from the payment or due payment every time it is paid or due. Such tax may be reduced or exempted pursuant to an applicable treaty for the avoidance of double taxation.

Pursuant to the Notice on the Issues Concerning Withholding the Enterprise Income Tax on the Dividends Paid by Chinese Resident Enterprises to H Share Holders Which Are Overseas Non-resident Enterprises (《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稅有關問題的通知》) issued by the State Administration of Taxation and effective on November 6, 2008, a PRC resident enterprise is required to withhold enterprise income tax at a rate of 10% on dividends paid to non-PRC resident enterprise holders of H Shares which are derived out of profit generated since 2008. The Reply on the Collection of Enterprise Income Tax on Dividends Received by Non-resident Enterprises from Holding B Shares and Other Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批

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覆》) promulgated by the State Administration of Taxation and effective July 24, 2009 further provides that PRC-resident enterprises listed on Chinese and overseas stock exchanges by issuing stocks (including A shares, B shares and overseas shares) must withhold enterprise income tax at a flat rate of 10% on dividends of 2008 and onwards that it distributes to non-resident enterprise shareholders. Such tax rates may be further modified pursuant to the tax treaty or agreement that China has concluded with a relevant jurisdiction, where applicable.

According to the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安 排》), the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total dividends payable by the PRC company. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC company and the Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total dividends payable by the PRC company. The Fifth Protocol provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including HKSCC Nominees). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty 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' verification.

Tax related to equity transfer income

Individual Investors

Under the Individual Income Tax Law and its implementation rules, individuals are subject to individual income tax at a rate of 20% on gains realized on the sale of equity interests in PRC resident enterprises. Pursuant to the Circular on Continuing the Temporary Exemption of Individual Income Tax on Gains from Share Transfers by Individuals (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》), which was promulgated by the MOF and The State Administration of Taxation and became effective on March 30, 1998, from January 1, 1997, income of individuals from the transfer of shares in listed companies continues to be temporarily exempted from individual income tax. The State Administration of Taxation does not specify whether to continue to exempt individuals from personal income tax on the income from the transfer of shares in listed company in the newly revised EIT Law and Implementation Rules of the EIT Law.

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Enterprise Investors

Under the EIT Law and its implementation rules, a non-PRC resident enterprise is subject to enterprise income tax at the rate of 10% with respect to PRC-sourced income, including gains derived from the disposal of shares in a PRC resident enterprise, if it does not have an establishment or premises in the PRC or has an establishment or premises in the PRC but the PRC-sourced income is not actually connected with such establishment or premises in the PRC. The aforementioned income tax payable by non-PRC resident enterprises is subject to source withholding, and the payer is the withholding agent. The tax shall be withheld by the withholding agent from the payment or due payment every time it is paid or due. Such tax may be reduced or exempted under applicable tax treaties or arrangements.

Shanghai-Hong Kong Stock Connect Taxation Policy

Pursuant to the Notice on the Tax Policies Related to the Pilot Program of the Shanghai-Hong Kong Stock Connect (《關於滬港股票市場交易互聯互通機制試點有關稅收政策的通知》) promulgated by the Ministry of Finance, the State Administration of Taxation and the CSRC on October 31, 2014 and effective on November 17, 2014, transfer spread income derived by mainland enterprises from stock investment listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect shall be included in their total income and subject to enterprise income tax according to law. For dividends and bonuses received by mainland individual investors from investing in H shares listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect, the H-share companies shall apply to CSDC for providing the register of mainland individual investors to the H-share companies and withhold individual income tax at the rate of 20% on behalf of the H-share companies.

Pursuant to the Announcement on Continuing the Implementation of the Individual Income Tax Policies Concerning the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and the Mainland-Hong Kong Mutual Recognition of Funds (《關於繼續執行滬港、深港股票市場交易互聯互通機制和內地與香港基金互認有關個人所得稅政策的公告》) promulgated by the Ministry of Finance, the State Administration of Taxation and the CSRC on December 4, 2019 and effective on December 5, 2019, the transfer spread income derived by mainland individual investors from investing in shares listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect shall be exempted from individual income tax from December 5, 2019 to December 31, 2022.

Pursuant to the Notice on the Tax Policies Related to the Pilot Program of the Shanghai-Hong Kong Stock Connect (《關於滬港股票市場交易互聯互通機制試點有關稅收政策的通知》), dividends derived by mainland enterprises from investing in shares listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect are included in their total income and subject to Enterprise Income Tax according to law. Pursuant to which, dividend income obtained by mainland resident enterprises from holding H shares for 12 consecutive months shall be exempted from enterprise income tax according to law. H-share companies shall not withhold income tax on dividends and bonus income for mainland enterprises investors. The tax payable shall be declared and paid by the enterprise itself.

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Shenzhen-Hong Kong Stock Connect Taxation Policy

Pursuant to the Notice on the Tax Policies Related to the Pilot Program of the Shenzhen-Hong Kong Stock Connect (《關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》) promulgated by the Ministry of Finance, the State Administration of Taxation and the CSRC on November 5, 2016 and effective on December 5, 2016, transfer spread income derived by mainland enterprises from stock investment listed on the Hong Kong Stock Exchange through Shenzhen-Hong Kong Stock Connect shall be included in their total income and subject to enterprise income tax according to law. For dividends and bonuses received by mainland individual investors from investing in H shares listed on the Hong Kong Stock Exchange through Shenzhen-Hong Kong Stock Connect, the H-share companies shall apply to CSDC for providing the register of mainland individual investors to the H-share companies and the H-share companies shall withhold individual income tax at the rate of 20% on behalf of the investors.

Pursuant to the Announcement on Continuing the Implementation of the Individual Income Tax Policies Concerning the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and the Mainland-Hong Kong Mutual Recognition of Funds promulgated by the Ministry of Finance of the PRC (the “MOF”), the State Administration of Taxation and the CSRC on December 4, 2019 and effective on December 5, 2019, individual income tax will be temporarily exempted for transfer spread income derived from investment by mainland individual investors in stocks listed on the Hong Kong Stock Exchange through the Shenzhen-Hong Kong Stock Connect from December 5, 2019 to December 31, 2022.

Pursuant to the Notice on the Tax Policies Related to the Pilot Program of the Shenzhen-Hong Kong Stock Connect (《財政部、國家稅務總局、證監會關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》), dividends derived by mainland enterprises investors from investing in shares listed on the Hong Kong Stock Exchange through Shenzhen-Hong Kong Stock Connect are included in their total income and subject to Enterprise Income Tax according to law. In particular, dividend and bonus income obtained by mainland resident enterprises from holding H shares for 12 consecutive months shall be exempted from enterprise income tax according to law. H-share companies shall not withhold income tax on dividends and bonus income for mainland enterprises. The tax payable shall be declared and paid by the enterprise itself.

Others

PRC Stamp Duty

According to the Stamp Duty Law of the People’s Republic of China (《中華人民共和國印花稅法》), which was promulgated on June 10, 2021 and came into effect on July 1, 2022, the disposal of H Shares by non-PRC investors outside of the PRC is not subject to the requirements of the Stamp Duty Law of the People’s Republic of China.

Estate duty

According to PRC law, no estate duty is currently levied in the PRC.

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MAJOR TAXATION OF THE COMPANY IN THE PRC

Enterprise Income Tax

According to the Enterprise Income Tax Law of the People’s Republic of China (中華人民共和國企業所得稅法), enterprises and other income-generating organizations (hereinafter collectively referred to as “enterprises”) within the territory of the People’s Republic of China are the taxpayers of enterprise income tax and shall pay enterprise income tax in accordance with the provisions of the EIT Law. The Enterprise Income Tax rate is 25%.

Enterprises are classified into resident enterprises and non-resident enterprises. A non-resident enterprise that does not have an establishment or place of business in the PRC, or has an establishment or place of business in the PRC but the income has no actual connection to such establishment or place of business, shall pay enterprise income tax on its income within the PRC and withhold at source, where the payer is the withholding agent. The tax shall be withheld by the withholding agent from the payment or due payment every time it is paid or due. Meanwhile, any gains realized on the transfer of shares by such investors are subject to enterprise income tax and shall be withheld at source if such gains are regarded as income derived from the transfer of property within the PRC.

Value-added Tax

Pursuant to the Provisional Regulations on Value-added Tax of the PRC (中華人民共和國增值稅暫行條例) amended by the State Council and became effective on November 19, 2017 and the Detailed Rules for the Implementation of the Provisional Regulations on Value-added Tax of the PRC (中華人民共和國增值稅暫行條例實施細則) amended by the MOF on October 28, 2011 and effective on November 1, 2011, all entities and individuals in the PRC engaging in the sale of goods, the provision of processing, repairs and replacement services, and the importation of goods are required to pay value-added tax. For taxpayers selling or importing goods, the general tax rate shall be 17% unless otherwise specified in the aforesaid regulations.

According to the Notice on the Adjustment to VAT Rates (《關於調整增值稅稅率的通知》) (Cai Shui [2018] No. 32), promulgated by the MOF and the State Administration of Taxation on April 4, 2018, and became effective as of May 1, 2018, the VAT rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》) (2019 No. 39 of MOF, State Administration of Taxation and General Administration of Customs), promulgated by the MOF, the State Administration of Taxation and the General Administration of Customs on March 20, 2019 and became effective on April 1, 2019, the VAT rates of 16% and 10% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 13% and 9%, respectively.

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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 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.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

FOREIGN EXCHANGE ADMINISTRATION IN THE PRC

The lawful currency of the PRC is the Renminbi, which is subject to foreign exchange controls and is not freely convertible. The State Administration of Foreign Exchange (the “SAFE”), authorized by 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.

Pursuant to the Regulations of the People’s Republic of China on Foreign Exchange Control (《中華人民共和國外匯管理條例》) amended by the State Council and became effective on August 5, 2008, all international payments and transfers are classified into current account items and capital account items. The PRC does not impose restrictions on international payments and transfers under current account items. Foreign exchange income from the current account of PRC enterprises may be retained or sold to financial institutions engaged in the settlement and sale of foreign exchange in accordance with relevant provisions of the State. The retention or sale of foreign exchange receipts under capital accounts to financial institutions engaging in settlement and sale of foreign exchange shall be subject to the approval of foreign exchange administrative authorities, unless otherwise stipulated by the State.

Pursuant to the Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) promulgated by the PBOC on June 20, 1996 and became effective on July 1, 1996, the remaining restrictions on convertibility of foreign exchange in respect of current account items are abolished while the existing restrictions on foreign exchange transactions in respect of capital account items are retained.

According to relevant laws and regulations of the PRC, PRC enterprises (including foreign-invested enterprises) which require foreign exchange for transactions relating to current account items, may, without the approval of SAFE, effect payment from their foreign exchange accounts at the designated foreign exchange banks, on the strength of valid receipts and proof of transactions. Foreign-invested enterprise that need to distribute profits to their shareholders in foreign exchange and Chinese enterprise that need to pay fixed dividends in foreign exchange in accordance with the requirements shall pay from its foreign exchange account or pay at the designated foreign exchange bank by a resolution of the board of directors on the distribution of profits.

According to 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) promulgated by the State Council and effective on October 23, 2014, the administrative approval of the SAFE and its branches on matters concerning the repatriation and settlement of foreign exchange of overseas-raised funds through overseas listing has been canceled.

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According to the Circular of the SAFE on Relevant Issues Concerning the Foreign Exchange Administration of Overseas Listing (國家外匯管理局關於境外上市外匯管理有關問題的通知) promulgated by the SAFE and became effective on December 26, 2014, the relevant provisions on foreign exchange administration of domestic joint stock companies (hereinafter referred to as “**domestic companies**”) listed overseas are as follows:

- (i) The SAFE and its branches and the Foreign Exchange Management Department (the “**Foreign Exchange Bureau**”) supervise, manage and inspect the business registration, account opening and use, cross-border income and expenditure, and capital exchange involved in the overseas listing of domestic companies.
- (ii) A domestic company shall, within 15 working days after the completion of the overseas listing and issuance, register the overseas listing with the Foreign Exchange Bureau at the place where it is registered with relevant material.
- (iii) After the overseas listing of a domestic company, its domestic shareholders who intend to increase or reduce their shareholding in an overseas listed company according to relevant regulations shall register the overseas shareholding with the local foreign exchange bureau at the place where the domestic shareholders are located within 20 working days prior to the proposed increase or reduction of shareholding with relevant materials.
- (iv) A domestic company (other than banking financial institutions) shall, by virtue of its registration certificate for overseas listing business, open a “special foreign exchange account for overseas listing of domestic companies” with a domestic bank for its initial offering (or additional offering) and repurchase business to handle the remittance and transfer of funds for the relevant business.

According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) issued on February 13, 2015 and came into effect on June 1, 2015, the SAFE has canceled the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment, instead, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionize and Regulate Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) issued and implemented by the SAFE on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjustment by the SAFE in due time in accordance with international revenue and expenditure situations.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

This Appendix summarizes certain aspects of PRC laws and regulations which are relevant to the Company’s operations and business. Laws and regulations relating to taxation in the PRC are discussed separately in “Appendix III – Taxation and Foreign Exchange” to this Document. This Appendix also contains a summary of certain material differences between laws and regulatory provisions of Hong Kong and the PRC Company Law. The principal objective of this summary is to provide potential investors with an overview of the principal laws and regulatory provisions applicable to the Company. This summary is not intended to include all the information which is important to the potential investors. For a discussion of laws and regulations which are relevant to the Company’s business, please refer to the section headed “Regulatory Overview” in this Document.

THE PRC LEGAL SYSTEM

The PRC legal system is based on the PRC Constitution (《中華人民共和國憲法》) (the “**Constitution**”) and is made up of written laws, administrative regulations, local regulations, separate regulations, rules and regulations of departments of the State Council, rules and regulations of local governments, autonomous regulations, separate regulations of autonomous regions, special administrative region law and international treaties and other regulatory documents signed by the PRC government. Court decisions do not constitute binding precedents, although they are used for the purposes of judicial reference and guidance.

According to the Constitution and the Legislation Law of the People’s Republic of China (《中華人民共和國立法法》) (the “**Legislation Law**”), which was amended by the NPC and became effective on March 15, 2015, the NPC and the SCNPC are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing criminal and civil matters, state organs and other matters. The SCNPC is empowered to formulate and amend laws other than those required to be enacted by the NPC and to supplement and amend any parts of laws enacted by the NPC during the adjournment of the NPC, provided 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 provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their standing committees may formulate local regulations on matters 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 such provinces or autonomous regions. Where laws have other stipulations on matters of local regulations formulated by cities divided into districts, such stipulations shall prevail. The local regulations of cities divided into autonomous regions for approval before implementation.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The standing committees of the people’s congresses of provinces or autonomous regions shall examine the legality of local regulations submitted for approval, and such approval should be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. People’s congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in the light of the political, economic and cultural characteristics of the nationality (nationalities) in the areas concerned. The ministries, commissions, PBOC, NAO of the State Council and institutions with administrative functions directly under the State Council may formulate rules and regulations within the jurisdiction of their respective departments based on the laws and the administrative regulations, decisions and rulings of the State Council.

The Constitution has supreme legal authority and no laws, administrative regulations, local regulations, autonomous regulations or separate regulations or rules may contravene the Constitution. The authority of laws is greater than that of administrative regulations, local regulations and rules. The authority of administrative regulations is greater than that of local regulations and rules. The authority of the rules enacted by the people’s governments of the provinces and autonomous regions is greater than that of the rules enacted by the people’s governments of the cities divided into districts within their respective administrative regions.

The NPC has the power to alter or annul any inappropriate laws enacted by the SCNPC, and to annul any autonomous regulations and separate regulations which have been approved by the SCNPC but which contravene the Constitution and the Legislation Law; the SCNPC has the power to annul administrative regulations that contravene the Constitution and laws, to annul local regulations that contravene the Constitution, laws and administrative regulations, and to annul autonomous regulations and separate regulations which have been approved by the standing committees of the people’s congresses of the relevant provinces, autonomous regions or municipalities directly under the Central Government, but which contravene the Constitution and the Legislation Law; the State Council has the power to alter or annul any inappropriate ministerial rules and rules of local governments; the people’s congresses of provinces, autonomous regions and municipalities directly under the Central Government have the power to alter or annul any inappropriate local regulations enacted or approved by their respective standing committees; the standing committees of the local people’s congresses have the power to annul inappropriate rules enacted by the people’s governments at the corresponding level; the people’s governments of provinces and autonomous regions have the power to alter or annul any inappropriate rules enacted by the people’s governments at a lower level.

According to the Constitution and the Legislation Law, the power to interpret laws is vested in the SCNPC. According to the Decision of the SCNPC Regarding the Strengthening of Interpretation of Laws (《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 by the SCNPC and effective on June 10, 1981, the Supreme People’s Court shall give interpretation on questions involving the specific application of laws and decrees in court trials. The Supreme People’s Procuratorate shall interpret all issues involving the specific application of laws and decrees in the procuratorial work. Interpretation of questions involving the specific application of laws and decrees in areas unrelated to judicial and procuratorial work shall be provided by the State Council and competent authorities.

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Where the scope of local regulations needs to be further defined or additional stipulations need to be made, the standing committees of the people’s congresses of provinces, autonomous regions and municipalities directly under the Central Government which have enacted these regulations shall provide the interpretations or make the stipulations. Interpretation of questions involving the specific application of local regulations shall be provided by the competent departments of the people’s governments of provinces, autonomous regions and municipalities.

PRC JUDICIAL SYSTEM

According to the Constitution and the Law of the PRC of Organization of the People’s Courts (《中華人民共和國人民法院組織法》) amended by the SCNPC on October 26, 2018 and becoming effective on January 1, 2019, the PRC People’s Court is made up of the Supreme People’s Court, the local people’s courts, and other special people’s courts. The local people’s courts 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.

According to The Constitution and the Law of Organization of the People’s Procuratorate of the PRC (《中華人民共和國人民檢察院組織法》) revised by SCNPC on October 26, 2018 and taking effect on January 1, 2019, the People’s Procuratorate is the law supervision organ of the state. 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.

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The PRC Civil Procedure Law (《中華人民共和國民事訴訟法(2021年修訂)》) (the “**PRC Civil Procedure Law**”) adopted by the SCNPC on December 24, 2021 and effective on January 1, 2022 sets forth the requirements for instituting a civil action, the jurisdiction of the people’s courts, the procedures to be followed for conducting a civil action and the procedures for enforcement of a civil judgment or order. All parties to a civil action conducted within the PRC must comply with the PRC Civil Procedure Law. Civil cases are generally heard by the courts where the defendants are located. The court of jurisdiction in a civil action may be chosen by express agreement between the parties, provided that the court is located at a place that has direct connection with the dispute, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is performed or signed or the object of the action is located. However, the choice of the court cannot be in conflict with the regulations of different jurisdictions and exclusive jurisdictions in any case.

A foreign individual, a person without nationality, a foreign-invested enterprise or a foreign organization must have the same litigation rights and obligations as a PRC citizen, legal person or other organizations when initiating or defending any proceedings at a people’s court. If a foreign court limits the litigation rights of PRC citizens and enterprises, the PRC court may apply the same limitations to the citizens and enterprises of such foreign country. A foreign individual, a person without nationality, a foreign-invested enterprise or a foreign organization must engage a PRC lawyer if such person needs to engage a lawyer in initiating or defending any proceedings at a people’s court. Under an international treaty or the principle of reciprocity signed or acceded to by the PRC, the people’s court and foreign courts may require each other to act on their behalf to serve documents, conduct investigations, collect evidence and take other actions on behalf of each other. If the request by a foreign court would result in the violation of the PRC’s sovereignty, security or public interest, the people’s court shall decline the request.

All parties must comply with legally effective civil judgments and rulings. If any party to a civil action refuse to comply with a judgment or order 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 enforcement within two years. Suspension or disruption of the time limit for applying for such enforcement shall comply with the provisions of the applicable law concerning the suspension or disruption of the time-barring of actions.

When a party applies to a people’s court for enforcing an effective judgment or ruling by a people’s court against a party who is not located within the territory of the PRC or whose property is not within the PRC, the party may apply to a foreign court with proper jurisdiction for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people’s court according to the PRC enforcement procedures if the PRC has entered into, or acceded to, an international treaty with the relevant foreign country, which provides for such recognition and enforcement, or if the judgment or ruling satisfies the court’s examination according to the principle of reciprocity, unless the people’s court finds that the recognition or enforcement of such judgment or ruling will result in a violation of the basic legal principles of the PRC, its sovereignty or security, or for reasons of social and public interests.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

THE PRC COMPANY LAW, TRIAL MEASURES AND GUIDELINES FOR ARTICLES OF ASSOCIATION

A joint stock limited company incorporated in the PRC seeking a listing on The Stock Exchange of Hong Kong Limited is mainly subject to the following laws and regulations of the PRC:

The PRC Company Law (《中華人民共和國公司法》) (the “**Company Law**”) was adopted by the Fifth Standing Committee Meeting of the Eighth NPC on December, 29 1993 and came into effect on July 1, 1994, and was amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. The latest revised Company Law came into effect on October 26, 2018.

The Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Trial Measures**”) and five relevant guidelines were promulgated by the CSRC on February 17, 2023 and implemented on March 31, 2023. The Trial Measures were applicable to the direct and indirect overseas share subscription and listing of domestic companies.

According to the Trial Measures and its interpretative guidelines, where a domestic company directly offering and listing overseas, it shall formulate its articles of association in line with the Guidelines for Articles of Association of Listed Companies (《上市公司章程指引》) (the “Guidelines for Articles of Association”) in place of the Mandatory Provisions for Articles of Association of Companies to be Listed Overseas which ceased to apply from March 31, 2023. The Guidelines for Articles of Association were promulgated by the CSRC on December 16, 1997 and last amended on January 5, 2022.

Set out below is a summary of the major provisions of the Company Law, the Trial Measures and the Guidelines for Articles of Association which are applicable to the Company.

General Provisions

“A joint stock limited company” means is a corporate legal person incorporated under the Company Law, whose registered capital is divided into shares of equal par value. The liability of its shareholders is limited to the extent of the shares held by them and the liability of a company is limited to the full value of all the property owned by it.

A company must conduct its business in accordance with laws as well as public and commercial ethics. A company may invest in other limited liability companies. The liabilities of the company to such invested companies are limited to the amount invested. Unless otherwise provided by laws, a company cannot be the capital contributor who has the joint liabilities associated with the debts of the invested enterprises.

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Incorporation

A joint stock limited company may be incorporated by promotion or subscription. A joint stock limited company may be incorporated by a minimum of two but not more than 200 promoters, and at least half of the promoters must have residence within the PRC.

The promoters shall convene an inaugural meeting of the company within 30 days after the share capital has been paid-up and shall notified all subscribers the date of the meeting or make an announcement in this regard 15 days before the meeting. The inaugural meeting may be held only in the presence of promoters and subscribers holding more than 50% of the total number of shares. Powers to be exercised at the inaugural meeting include but not limited to the adoption of articles of association and the election of members of the board of directors and the supervisory committee of a company. The aforesaid matters shall be resolved by more than 50% of the votes to be casted by subscribers presented at the meeting.

Within 30 days after the conclusion of the inaugural meeting, the board of directors shall apply to the registration authority for registration of the incorporation of the joint stock limited company. A company is formally established and has the status of a legal person after the business license has been issued by the relevant registration authority. A joint stock limited company established by the subscription method shall obtain the approval for public offering from the securities regulatory authority of the State Council and submit the approval to the company registration authority.

A joint stock limited company’s promoters shall be liable for: (1) the payment of debts and expenses incurred in the incorporation process jointly and severally if a company cannot be incorporated; (2) the refund of subscription monies paid by the subscribers, together with interest, at bank rates of deposit for the same period jointly and severally if a company cannot be incorporated; and (3) the compensation of any damages suffered by a company as a result of the default of the promoters in the course of its establishment. According to the Interim Provisional Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行條例》) promulgated by the State Council on April 22, 1993 (which is only applicable to the issuance and trading of shares in the PRC and their related activities), if a company is established by means of public subscription, the promoters of such company are required to sign on the prospectus to ensure that the prospectus does not contain any misrepresentation, serious misleading statements or material omissions, and assume joint and several responsibility for it.

Registered Shares

Under the Company Law, shareholders may make capital contributions in cash, or with non- monetary property that may be valued in money and legally transferred, such as contribution in kind or with an intellectual property rights or land use rights.

The Trial Measures provides that domestic enterprises that are listed overseas may raise funds and distribute dividends in foreign currencies or Renminbi.

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Under the Trial Measures, for a domestic company directly offering and listing overseas, shareholders of its domestic unlisted shares applying to convert such shares into shares listed and traded on an overseas trading venue shall conform to relevant regulations promulgated by the CSRC, and authorize the domestic company to file with the CSRC on their behalf. The domestic unlisted shares mentioned in the preceding paragraph refer to the shares that have been issued by domestic enterprises but have not been listed or listed for trading on domestic exchanges. Domestic unlisted shares shall be centrally registered and deposited with domestic securities registration and settlement institutions. The registration and settlement arrangements of overseas listed shares shall be subject to the provisions of overseas listing places.

Under the Company Law, when a company issues shares in registered form, it shall maintain a register of shareholders, stating the following matters: (1) the name and domicile of a shareholder; (2) the number of shares held by each shareholder; (3) the serial number of the shares held by each shareholder; and (4) the date on which each shareholder acquired the shares.

Allotment and Issue of Shares

All issue of shares of a joint stock limited company shall be based on the principles of equality and fairness. The same class of shares 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. It may issue shares at par value or at a premium, but it may not issue shares below the par value.

Domestic enterprises issued and listed overseas shall file with the CSRC in accordance with Trial Measures, submit filing reports, legal opinions and other relevant materials, and truthfully, accurately and completely explain shareholder information and other information. Where a domestic enterprise directly issues and is listed overseas, the issuer shall file with the CSRC. If a domestic enterprise is indirectly listed overseas, the issuer shall designate a major domestic operating entity as the domestic responsible person and file with the CSRC.

Increase in Share Capital

Under the Company Law, in the case of a joint stock limited company issuing new shares, resolutions shall be passed at the shareholders’ general meeting in respect of the class and number of new shares, the issue price of the new shares, the commencement and end dates for the issuance of new shares and the class and number of the new shares proposed to be issued to existing shareholders. When a company launches a public offering of new shares under the permission of the securities regulatory authority of the State Council, it must publish a prospectus for the new shares and financial and accounting reports, and prepare the share subscription form. After payment in full for the new shares issued, a company must change its registration with a company registration authority and make an announcement accordingly.

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Reduction of Share Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the Company Law:

- (i) to prepare a balance sheet and a property list;
- (ii) a company makes a resolution at shareholders’ general meeting to reduce its registered capital;
- (iii) a company shall inform its creditors within 10 days and publish an announcement in newspapers within 30 days after the approval of resolution of reducing registered capital;
- (iv) the creditors shall have the right to require a company to repay its debts or provide corresponding guarantees within 30 days after receiving the notice or within 45 days after the announcement if the creditors have not received the notice;
- (v) when a company reduces its registered capital, it shall register the change with a company registration authority in accordance with the law.

Share Buy-Back

Under the Company Law, a company shall not purchase its own shares. Except for any following circumstances:

- (i) reducing the registered capital;
- (ii) merging with other company that holds the shares of the Company;
- (iii) using the shares for employee stocks plan or equity incentives;
- (iv) with respect to shareholders voting against any resolution adopted at the shareholders’ general meeting on the merger or division of our Company, the right to demand our Company to acquire the shares held by them;
- (v) using the shares for the conversion of convertible corporate bonds issued by the listed company;
- (vi) as required for maintenance of the corporate value and shareholders’ rights and interests of a listed company.

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The purchase of shares of a company for reasons specified in the case of (i) to (ii) above shall be subject to the resolution of the general meeting; the purchase of shares of a company for reasons specified in the case of (iii), (v) and (vi) above shall be subject to the resolution of the Board meeting attended by more than two-thirds of the directors in accordance with the provisions of the Articles of Association or the authorization from the general meeting.

Following the purchase of a company’s shares by a company in accordance with the above provisions, such shares shall be canceled within 10 days from the date of buy-back in the case of item (i) above; such shares shall be transferred or canceled within six months in the case of items (ii) and (iv) above; the total numbers of share of our Company held by a company shall not exceed 10% of the total issued shares of a company, and shall be transferred or canceled within three years in the case of items (iii), (v) and (vi) above.

Transfer of Shares

Shares held by a shareholder may be transferred according to the law. Under the Company Law, a shareholder should affect a transfer of his shares on securities established exchange according to the law or by any other means as required by the State Council. Registered shares may be transferred by endorsement of shareholders or by other means stipulated by laws or administrative regulations. After the transfer, a company shall record the name and address of the transferee in the register of shareholders. No changes of registration in the share register provided in the foregoing requirement shall be affected during a period of 20 days prior to the convening of shareholder’s general meeting or 5 days prior to the record date for a company’s distribution of dividends. However, if any law provides otherwise for the registration of changes in the register of members of a listed company, such provisions shall prevail. The transfer of bearer share certificates shall become effective upon delivery of such share certificates to the transferee by the shareholder.

Under the Company Law, shares in the Company held by promoters shall not be transferred within one year after the date of establishment of a company. Shares issued by a company prior to the public offering of shares shall not be transferred within one year from the date on which the shares of accompany are listed and traded on a securities exchange. Directors, Supervisors and senior management of a company shall declare to a company their shareholdings in a company and any changes of such shareholdings, and the shares transferred each year during their term of office shall not exceed 25% of the total shares they hold in a company. Shares of a company held by its directors, supervisors and senior management shall not be transferred within one year from the date of a company’s listing on a securities exchange, nor within six months after their resignation from their positions with a company.

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Shareholders

Under the Company Law and the Guidelines for Articles of Association, the rights of a shareholder of ordinary shares of a company include:

- (i) to receive dividends and other forms of distributions in proportion to their shareholdings;
- (ii) to attend or appoint a proxy to attend shareholders’ general meetings and to exercise voting rights;
- (iii) to supervise and manage a company’s business operations, and to present proposals or to raise inquiries;
- (iv) to transfer shares in accordance with laws, administrative regulations and the provisions of the Articles of Association;
- (v) to inspect the company’s articles of association, share register, counterfoil of company debentures, minutes of shareholder’s general meetings, resolutions of meetings of the board of directors, resolutions of meetings of the board of supervisors and financial and accounting reports and to make proposals or enquires on the company’s operations;
- (vi) in the event of the winding-up or liquidation of a company, to participate in the distribution of remaining property of a company in proportion to the number of shares held;
- (vii) other rights conferred by laws, administrative regulations and the Articles of Association.

The obligations of a shareholder of ordinary shares of a company include:

- (i) to comply with the Articles of Association;
- (ii) to pay subscription money according to the number of shares subscribed and the method of subscription;
- (iii) not to abuse their shareholders’ rights to damage the interests of a company or other shareholders; not to abuse the independent legal person status of a company and the limited liability of shareholders to damage the interests of the creditors of a company;
- (iv) other obligations conferred by laws, administrative regulations and the Articles of Association.

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Shareholder’s General Meetings

Under the Company Law, the shareholders’ general meeting of a joint stock limited company is made up of all shareholders. The shareholders’ general meeting is the organ of authority of a company, which exercises the following functions and powers:

- (i) to decide on a company’s business policies and investment plans;
- (ii) to elect and replace directors and supervisors who are not representatives of the employees and to decide on matters relating to the remuneration of directors and supervisors;
- (iii) to examine and approve reports of the board of directors;
- (iv) to examine and approve reports of the supervisory committee or supervisors;
- (v) to examine and approve a company’s annual financial budget and final accounts;
- (vi) to examine and approve a company’s profit distribution plans and loss recovery plans;
- (vii) to resolve on the increase or reduction of a company’s registered capital;
- (viii) to resolve on the issuance of corporate bonds;
- (ix) to resolve on the merger, division, dissolution, liquidation or change of corporate form of a company;
- (x) to amend the a company’s Articles of Association;
- (xi) other functions and powers specified in provision of the Articles of Association.

Under the Company Law, annual shareholders’ general meetings are required to be held once every year. An extraordinary shareholders’ general meeting is required to be held within two months after the occurrence of any of the following circumstances:

- (i) the number of directors is less than the number stipulated in the Company Law or less than two-thirds of the number specified in the Articles of Association;
- (ii) when the unrecovered losses of a company amount to one-third of the total paid-up share capital;
- (iii) shareholders individually or jointly holding 10% or more of the company’s shares request;

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- (iv) when deemed necessary by the Board;
- (v) the Supervisory Committee proposes to convene the meeting;
- (vi) other circumstances as stipulated in the Articles of Association.

Shareholders' general meetings 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 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 not performing his duties, a director nominated by more than half of directors shall preside over the meeting.

Where the board of directors is incapable of performing or is not performing its duties to convene the general meeting, the supervisory board shall convene and preside over shareholders' general meeting in a timely manner. If the supervisory board fails to convene and preside over 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 shareholders' general meeting.

Notice of general meeting shall state the time and venue of and matters to be considered at the meeting and shall be given to all shareholders 20 days before 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 before the meeting.

Pursuant to the Guidelines for Articles of Association, shareholders who individually or jointly hold more than 3% of the company's shares may put forward interim proposals and submit them to the convener in writing 10 days before the general meeting of shareholders. The convener shall issue a supplementary notice of the general meeting of shareholders within two days after receiving the proposal and announce the contents of the interim proposal.

Under the Company Law, a shareholder may entrust a proxy to attend a shareholders' general meeting. The proxy shall present a written power of attorney issued by the shareholder to a company and shall exercise his voting rights within the scope of authorization. There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum in a shareholders' general meeting.

Under the Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that shares held by a company are not entitled to any voting rights.

The cumulative voting system may be adopted for the election of directors and supervisors at the shareholders' general meeting in accordance with the provisions of the Articles of Association or the resolutions of the shareholders' general meeting. Under the

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accumulative voting system, each share shall have the same number of voting rights as the number of directors or supervisors to be elected at the shareholders’ general meeting, and shareholders may consolidate their voting rights when casting a vote.

Under the Company Law and the Guidelines for Articles of Association, the passing of any resolution requires affirmative votes of shareholders representing more than half of the voting rights represented by the shareholders who attend the shareholders’ general meeting. Matters relating to merger, division or dissolution of a company, increase or reduction of registered capital, change of corporate form or amendments to the articles of association must be approved by more than two-thirds of the voting rights held by the shareholders present at the meeting.

Directors

Under the Company Law, a joint stock limited company shall have a board of directors, which shall consist of five to nineteen members. The term of office of a director shall be stipulated in the Articles of Association, but each term of office shall not exceed three years. Directors may serve consecutive terms if re-elected.

Meetings of the board of directors shall be convened at least twice a year. All directors and supervisors shall be noticed 10 days before the meeting for every meeting. The Board exercises the following functions and powers:

- (i) to convene shareholder’s general meetings and report its work to the shareholder’s general meetings;
- (ii) to implement the resolutions of the shareholder’s general meeting;
- (iii) to decide on a company’s business plans and investment plans;
- (iv) to formulate a company’s annual financial budget and final accounts;
- (v) to formulate a company’s profit distribution plan and loss recovery plan;
- (vi) to formulate proposals for the increase or reduction of a company’s registered capital and the issue of corporate bonds;
- (vii) to formulate plans for merger, division, dissolution or change of corporate form of a company;
- (viii) to decide on the internal management structure of a company;
- (ix) to decide on the appointment or dismissal of the manager of a company and their remuneration;

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- (x) To decide on the appointment or dismissal of the deputy manager and financial officer of a company based on the nomination of the manager and as well as remuneration;
- (xi) to formulate a company's basic management system;
- (xii) other functions and powers specified in the Articles of Association.

Board meetings shall be held only if more than half of the directors are present. If a director is unable to attend a board meeting, he may appoint another director by a power of attorney specifying the scope of the authorization for another director to attend the meeting on his behalf. If a resolution of the board of directors violates the laws, administrative regulations or the Articles of Association, and as a result of which the company suffers serious losses, the directors participating in the resolution shall be 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 may be exempt from such liability.

Under the Company Law, a person may not serve as a director of a company if he is:

- (i) a person without capacity or with restricted capacity;
- (ii) a person who has been sentenced to criminal punishment due to corruption, bribery, infringement of property, misappropriation of property or destruction of the socialist market economic order, where less than five years have elapsed since the date of completion of the sentence; or a person who has been deprived of his political rights due to a crime, where less than five years have elapsed since the date of completion of the sentence;
- (iii) a person who was a director, factory manager or manager of a company or enterprise which 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 insolvency and liquidation of such company or enterprise;
- (iv) persons who were legal representatives of a company or enterprise which had its business license revoked due to violation of the law and had been closed down by order, and who were personally liable, where less than three years have elapsed since the date of the revocation of the business license of the company or enterprise; and
- (v) persons who have a relatively large amount of debts due and outstanding.

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The board of directors shall have one chairman, who shall be elected by more than half of all the directors. The chairman shall exercise the following functions and powers (including but not limited to):

- (i) to preside over shareholders’ general meetings and convene and preside over board meetings;
- (ii) to examine the implementation of resolutions of the Board;
- (iii) to sign the securities issued by a company;
- (iv) to exercise other powers conferred by the Board.

Supervisors

Under the Company Law, a joint stock limited company shall have a supervisory committee composed of not less than three members. The supervisory committee shall comprise shareholder representatives and an appropriate proportion of the company’s staff representatives, of which the proportion of staff representatives shall not be less than one-third and the specific proportion shall be stipulated in the Articles of Association. Employee representatives of the supervisory committee shall be democratically elected by the company’s employees at the employee representative assembly, employee general meeting or otherwise. Directors or senior management may not act concurrently as supervisors.

The Supervisory Committee exercises the following powers:

- (i) to examine the company’s financial affairs;
- (ii) 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, administrative regulations, the Articles of Association or resolutions of shareholders’ general meetings;
- (iii) to demand rectification by a director or senior management when the acts of such persons are harmful to the company’s interest;
- (iv) to propose the convening of extraordinary 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 Company Law;
- (v) to submit proposals to the shareholders’ general meeting;

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- (vi) to initiate legal proceedings against directors and senior management in accordance with the Company Law;
- (vii) other functions and powers specified in the Articles of Association.

Managers and Senior Management

Under the Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager is accountable to the board of directors and may exercise the following powers:

- (i) to be in charge of the production, operation and management of the company and to organize the implementation of the resolutions of the board of directors;
- (ii) to organize the implementation of the company’s annual business plans and investment plans;
- (iii) to formulate plans for the establishment of the company’s internal management structure;
- (iv) to draft the company’s basic management system;
- (v) to formulate the basic rules and regulations of the company;
- (vi) to propose the appointment or dismissal of the company’s deputy manager and financial controller;
- (vii) to appoint or dismiss management personnel other than those required to be appointed or dismissed by the board of directors; and
- (viii) to exercise other powers conferred by the Articles of Association and the Board.

According to the Company Law, senior management shall refer to the manager, deputy manager(s), financial controller, secretary of the board of directors and other personnel as stipulated in the Articles of Association of the company.

Duties of Directors, Supervisors and Senior Management

Directors, supervisors and senior management of the company are required under the Company Law to comply with the relevant laws, regulations and the articles of association, and have fiduciary and diligent duties to the company. Directors, supervisors and senior management are prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating the company’s properties.

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Directors and senior management are prohibited from:

- (i) misappropriation of the company's capital;
- (ii) depositing the company's capital into accounts under his own name or the name of other individuals;
- (iii) loaning company funds to others or providing guarantees in favor of others supported by the company's assets in violation of the articles of association or without prior approval of the shareholders' general meeting or board of directors;
- (iv) entering into contracts or deals with the company in violation of the articles of association or without prior approval of the shareholders' general meeting;
- (v) using their position and powers to procure business opportunities for themselves or others that should have otherwise been available to the company or operating for their own benefits or managing on behalf of others businesses similar to that of the company without prior approval of the shareholders' general meeting;
- (vi) accept and possess commissions paid by a third party for transactions conducted with the company;
- (vii) unauthorized divulgence of confidential business information of the company; or
- (viii) other acts in violation of their fiduciary duty to the company.

A director, supervisor or senior management who contravenes any law, regulation or the company's articles of association in the performance of his duties resulting in any loss to the company shall be personally liable for the damages to the company.

Finance and Accounting

Under the Company Law, a company shall establish its financial and accounting systems according to laws, administrative regulations and the regulations of the financial department of the State Council. At the end of each fiscal year, the Company shall prepare a financial and accounting reports which shall be audited by an accounting firm in accordance with the law. The financial and accounting reports shall be prepared in accordance with the laws, administrative regulations and the regulations of the financial department of the State Council.

A joint stock limited company shall make its financial and accounting reports available at the company for inspection by the shareholders 20 days before the convening of an annual general meeting of shareholders. A joint stock limited company issuing its shares in public must publish its financial and accounting reports.

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When distributing each year’s after-tax profits, the company shall set aside 10% of its profits into its statutory reserve fund. The company can no longer withdraw statutory reserve fund if it has accumulated to more than 50% of the registered capital. If the statutory reserve fund of the company is insufficient to make up for the losses of the previous years, the current year profits shall be used to make up for the losses before making allocations to the statutory reserve in accordance with the preceding paragraph. After the company has made an allocation to the statutory reserve fund from its after-tax profit, it may also make an allocation to the discretionary reserve fund from its after-tax profit upon a resolution of the general meeting or the shareholders’ general meeting.

A joint stock limited company may distribute profits in proportion to the number of shares held by its shareholders, except for profit distributions that are not in proportion to the number of shares held in accordance with the provisions of the Articles of Association of the joint stock limited company.

The premium over the nominal value of the shares of a joint stock limited company from the issue of shares and other incomes required by the financial department of the State Council to be treated as the capital reserve fund shall be accounted for as the capital reserve fund of the company.

The reserve fund of the company shall be used to make up losses of the company, expand the production and operation of the company or increase the capital of the company. However, the capital reserve shall not be used to make up the company’s losses. When the statutory reserve fund is converted into capital, the balance of the statutory reserve shall not be less than 25% of the registered capital before such conversion.

The company shall not keep accounts other than those provided by law.

Appointment and Dismissal of Accounting Firms

Pursuant to the 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 conduct 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 information.

The Guidelines for Articles of Association provides that the company guarantees to provide true and complete accounting vouchers, accounting books, financial accounting reports and other accounting materials to the employed accounting firm, and shall not refuse, conceal or falsely report. And the audit fee of the accounting firm shall be decided by the general meeting of shareholders.

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Profit Distribution

Under the Company Law, a company shall not distribute profits before losses are covered and the statutory reserve fund is drawn.

Dissolution and Liquidation

According to the Company Law, a company shall be dissolved for the following reasons:

- (i) the term of business stipulated in the Articles of Association has expired or other events of dissolution specified in the Articles of Association have occurred;
- (ii) the general meeting or the shareholders’ general meeting resolves to dissolve the company;
- (iii) dissolution is necessary due to a merger or division of the company;
- (iv) the business license is revoked, or the business license is ordered to be closed or revoked in accordance with laws;
- (v) where the company encounters serious difficulties in its operation and management and its continuance shall cause a significant loss in the interest of shareholders, and where this cannot be resolved through other means, shareholders who hold more than 10% of the total shareholders’ voting rights of the company may present a petition to a people’s court for the dissolution of the company with the support of the judgment.

Where the company is dissolved in accordance with sub-paragraph (i) above, it may carry on its existence by amending its articles of association, which must be approved by more than two-thirds of the voting rights held by the shareholders present at the shareholders’ general meeting. Where the Company is dissolved pursuant to sub-paragraphs (i), (ii), (iv) or (v) above, a liquidation committee shall be established and the liquidation shall commence within 15 days after the occurrence of an event of dissolution. The liquidation committee of a joint stock limited company shall be composed of directors or the personnel determined by a shareholders’ general meeting. If a liquidation committee is not established within the stipulated period to conduct liquidation, the creditors may apply to the people’s court to appoint relevant personnel to form a liquidation committee to conduct liquidation. The people’s court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee shall exercise the following functions and powers during the liquidation period:

- (i) to liquidate the company’s property and respectively prepare balance sheet and list of property;

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- (ii) to notify creditors by notice or public announcement;
- (iii) to deal with the outstanding business of the company involved in the liquidation;
- (iv) to pay all outstanding taxes and taxes arising in the course of liquidation;
- (v) to liquidate claims and debts;
- (vi) to deal with the remaining property of the company after paying off debts;
- (vii) to participate in civil litigations on behalf of the company.

The remaining property of the company after the payment of liquidation expenses, employees’ wages, social insurance expenses and statutory compensation, outstanding taxes and the company’s debts, shall be distributed to shareholders in proportion to their shareholdings.

During the liquidation period, the company shall continue to exist but shall not carry out any business activities unrelated to the liquidation. The company’s assets shall not be distributed to the shareholders before the liquidation in accordance with the preceding paragraph.

If the liquidation committee, having thoroughly examined the company’s assets and having prepared a balance sheet and an inventory of assets, discovers that the company’s assets are insufficient to pay its debts in full, it shall apply to the people’s court for a declaration of insolvency. After the people’s court has declared the company bankrupt, the liquidation committee shall hand over the affairs of the liquidation to the people’s court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report to be submitted to the shareholders’ general meeting or the people’s court for confirmation, and submit to the company registration authority to apply for cancelation of the company’s registration and to announce the termination of the company.

Members of the liquidation committee are required to discharge their duties honestly and 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. A member of the liquidation committee is liable to indemnify the company and its creditors in respect of any loss arising from his willful or material default.

Overseas Listing

According to the Trial Measures, where an issuer makes an overseas initial public offering or listing, it shall file with the CSRC within 3 working days after submitting the application documents for overseas issuance and listing. If an issuer issues securities in the same overseas

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market after overseas issuance and listing, it shall file with the CSRC within 3 working days after the completion of the issuance. If an issuer issues and lists in other overseas markets after overseas issuance and listing, it shall be filed in accordance with the provisions of the first paragraph of this article. Moreover, if the filing materials are complete and meet the requirements, the CSRC shall complete the filing within 20 working days from the date of receiving the filing materials, and publicize the filing information through the website. If the filing materials are incomplete or do not meet the requirements, the CSRC shall inform the issuer of the materials to be supplemented within 5 working days after receiving the filing materials. The issuer shall supplement the materials within 30 working days.

On November 14, 2019, CSRC promulgated the Notice on the Guidance of H-share Companies Applying for “Full Circulation” Business of Unlisted Shares in China (CSRC Announcement [2019] No. 22), which came into effect on the same day. This provision is to regulate the listing and circulation (hereinafter referred to as “**Full Circulation**”) of unlisted domestic shares of domestic joint-stock limited companies (hereinafter referred to as H-share Companies) listed on the stock exchange of Hong Kong (including unlisted domestic capital stock held by domestic shareholders before overseas listing, unlisted domestic capital stock issued in China after overseas listing and unlisted shares held by foreign shareholders) to the Hong Kong Stock Exchange.

H-share Companies applying for “Full Circulation” shall put forward the application to CSRC in accordance to the administrative licensing procedure of Examination and Approval of Overseas Public Offering and Listing (Including Additional Issuance) of Joint-Stock Limited Companies. H-share companies may put forward the application of “Full Circulation” separately or simultaneously when applying for overseas refinancing. Unlisted domestic joint-stock limited companies may put forward the application of “Full Circulation” simultaneously when applying for overseas initial public offering and listing.

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 declared that such certificate(s) will no longer be valid, the shareholder may apply to the company for the issue of a replacement certificate(s).

Suspension and Termination of Listing

The Company Law has deleted provisions governing suspension and termination of listing. The PRC Securities Law (2019 revision) (《中華人民共和國證券法(2019年修訂)》) has also deleted provisions regarding suspension of listing. Where listed securities fall under the delisting circumstances stipulated by the stock exchange, the stock exchange shall terminate its listing and trading in accordance with the business rules.

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According to the Trial Measures, in case of active or compulsory termination of listing, the issuer shall report the specific situation to the CSRC within 3 working days from the date of occurrence and announcement of the relevant matters.

SECURITIES LAW AND REGULATIONS

In October 1992, the State Council established the Securities Committee and the 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 the CSRC. The CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions of securities markets, supervising securities companies, regulating public offers of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking research and analysis. On March 29, 1998, the State Council consolidated the above two departments and reformed the CSRC.

The Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) promulgated by the State Council and effective on April 22, 1993 provide the application and approval procedures for public offerings of shares, trading in shares, the acquisition of listed companies, the deposit, settlement and transfer of listed shares, the disclosure of information with respect to a listed company, investigation and penalties and dispute arbitration.

The Regulations of the State Council Concerning the 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規定》), which were promulgated by the State Council and came into effect on December 25, 1995, mainly provide for the issue, subscription, trading and payment of dividends of domestic listed foreign shares and disclosure of information of joint stock limited companies with domestic listed foreign shares.

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》) (hereinafter referred to as the “**PRC Securities Law**”), which was amended by the Standing Committee of the NPC on December 28, 2019 and came into effect on March 1, 2020, provides a series of provisions regulating, among other things, the issue and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities in the PRC, and comprehensively regulates activities in the PRC securities market. The PRC Securities Law provides that a domestic enterprise must comply with the relevant provisions of the State Council in issuing securities directly or indirectly outside the PRC or listing and trading its securities outside the PRC. Currently, the issue and trading of foreign issued shares are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

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The Guidelines for the Application for “Full Circulation” of Domestic Unlisted Shares of H Share Companies (《H股公司境內未上市股份申請“全流通”業務指引》) issued by the CSRC and came into effect on November 14, 2019 regulates the listing and circulation of unlisted domestic shares of domestic stock companies (hereinafter referred to as “H share companies”) listed on the Hong Kong Stock Exchange (including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares issued in China upon overseas listing and unlisted shares held by overseas shareholders). The application for “full circulation” by H share companies shall be submitted to the CSRC for approval pursuant to the administrative approval procedures for “overseas public share offering and listing (including additional issuance) of joint stock limited companies”. When applying for overseas refinancing, H share companies may separately or concurrently apply for “full circulation”. A domestic joint stock limited company whose shares are unlisted may simultaneously make an application for “full circulation” at the time of applying for an overseas initial public issuance and listing.

ARBITRATION AND ENFORCEMENT OF ARBITRAL AWARDS

Under the Arbitration Law of the People’s Republic of China (《中華人民共和國仲裁法》) (hereinafter referred to as “**Arbitration Law**”) amended by the Standing Committee of the NPC on September 1, 2017 and effective on January 1, 2018, the Arbitration Law is applicable to economic disputes involving foreign parties, and all parties have entered into a written agreement to refer the matter to an arbitration committee constituted in accordance with the Arbitration Law. An arbitration committee may, before the promulgation by the PRC Arbitration Association of arbitration regulations, formulate interim arbitration rules in accordance with relevant regulations under the Arbitration Law and the PRC Civil Procedure Law. Where both parties have agreed to settle disputes by means of arbitration, the people’s court will refuse to take legal action brought by a party in the people’s court.

Under the Arbitration Law, an arbitral award is final and binding on the parties. If a party fails to comply with an award, the other party to the award may apply to the people’s court for enforcement according to the PRC Civil Procedure Law. A people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including irregularity in the composition of the arbitration committee or the making of an award on matters beyond the scope of the arbitration agreement or the jurisdiction of the arbitration commission). A party seeking to enforce an arbitral award of foreign arbitration commission against a party who or whose property is not within the PRC shall apply to a foreign court with jurisdiction over the case for recognition and enforcement. Similarly, an arbitral award made by a foreign arbitration body may be recognized and enforced by the people’s court in accordance with the principles of reciprocity or any international treaty concluded or acceded to by the PRC.

According to the Arrangement of the Supreme People’s Court on Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區相互執行仲裁裁決的安排》) promulgated by the

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Supreme People’s Court on January 24, 2000 and effective on February 1, 2000, and the Supplementary Arrangement of the Supreme People’s Court on Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區相互執行仲裁裁決的補充安排》) promulgated by the Supreme People’s Court on November 26, 2020 and effective on November 27, 2020, awards made by PRC arbitral authorities can be enforced in Hong Kong, and Hong Kong arbitration awards are also enforceable in the PRC.

SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND THE PRC COMPANY LAW

The Hong Kong law applicable to a company incorporated in Hong Kong is based on the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, supplemented by common law and the rules of equity that apply to Hong Kong. As a joint stock limited company established in the PRC that is seeking an initial listing of shares on the Stock Exchange, we are subject to the Company Law and all other rules and regulations promulgated pursuant to the Company Law.

Set out below is a summary of certain material differences between Hong Kong company law applicable to a company incorporated in Hong Kong and the Company Law applicable to a joint stock limited company incorporated and existing under the Company Law. This summary is, however, not intended to be an exhaustive comparison.

Corporate Existence

Under Hong Kong company law, a company with share capital must be incorporated by the Registrar of Companies in Hong Kong, which issues a certificate of incorporation to the company upon its incorporation, and the company will acquire an independent corporate existence. 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 certain pre-emptive provisions. A public company’s articles of association do not contain such pre-emptive provisions.

Under the Company Law, a joint stock limited company may be incorporated by promotion or public subscription. The minimum registered capital of a joint stock limited company is not required, unless otherwise provided by laws, administrative regulations and the decisions of the State Council, for the paid-up registered capital and the minimum registered capital of a joint stock limited company.

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Share Capital

Under the Companies Ordinance, the concept of the nominal value (also known as par value) of shares of a Hong Kong company has been abolished, and the companies have increased flexibility to alter its share capital by (1) increasing its share capital; (2) capitalizing its profits; (3) allotting and issuing bonus shares with or without increasing its share capital; (4) converting its shares into larger or smaller number of shares; and (5) canceling its shares. The concept of authorized capital no longer applies to a Hong Kong company formed on or after March 3, 2014 as well. Hence, the directors of a Hong Kong company may, with the prior approval of the shareholders, if required, cause the company to issue new shares. The Company Law does not provide for authorized share capital. The share capital of a company incorporated in Hong Kong would be its issued share capital. The full proceeds of a share issue will be credited to share capital and becomes the company’s share capital.

Under the PRC Securities Law, an application for listing shall comply with the listing rules of the stock exchange. Hong Kong law does not prescribe any minimum capital requirements for companies incorporated in Hong Kong.

Under the Company Law, shareholders may provide capital contribution 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 assets verification must be carried out to ensure no overvaluation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong law.

Restrictions on Shareholding and Transfer of Shares

Under PRC law, the Domestic Shares, which are denominated and subscribed for in Renminbi, can only be subscribed for and traded by PRC investors, designated qualified overseas institutional investors or qualified overseas strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a foreign currency, may only be subscribed for, and traded by, investors from countries and regions outside the PRC or other qualified PRC institutional investors. If the H Shares are eligible securities under the Southbound Trading Link, they are also available for subscription and trading by domestic investors in the PRC pursuant to the rules and restrictions of Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

Under the 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 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 the said personnel has left office.

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There are no such restrictions on shareholdings and transfers of shares under Hong Kong law apart from the six-month lockup on the company’s issue of shares and the 12-month lockup for the controlling shareholders (as defined under Listing Rules) disposal of shares, after [REDACTED].

Financial Assistance for Acquisition of Shares

Although the 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, the Guidelines for Articles of Association contain certain restrictions on a company and its subsidiaries on providing such financial assistance similar to those under Hong Kong company law.

Notice of Shareholders’ General Meeting

Under the Company Law, notice of a shareholders’ general meeting must be given not less than 20 days before the meeting, while notice of an extraordinary general meeting must be given not less than 15 days before the meeting. If a company has bearer shares, a public announcement of a shareholders’ general meeting must be made at least 30 days prior to the meeting.

For a limited 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. or a private company. Further, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting.

Quorum for Shareholders’ General Meetings

The Company Law does not specify any quorum requirement for a shareholders’ general meeting. Under Hong Kong law, the quorum for a shareholders’ general meeting is two members unless the articles of association of the company otherwise provide. For a single member company, one member is a quorum.

Voting at Shareholders’ General Meetings

Under the Company Law, the passing of any resolution requires more than half of the votes held by the shareholders present in person or by proxy. Amendments to the articles of association, change of corporate form, increase or decrease of registered capital and merger, division or dissolution must be approved by shareholders or proxies representing more than two-thirds of the voting rights being present in shareholders’ general meeting.

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SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Under Hong Kong law, (1) an ordinary resolution is passed by a simple majority of votes cast by members present in person or by proxy at a shareholders’ general meeting and (2) a special resolution is passed by a majority of not less than three-fourths of votes cast by members present in person or by proxy at a shareholders’ general meeting.

Variation of Class Rights

The Company Law has no special provision relating to variation of class rights. However, the Company Law states that the State Council can promulgate regulations relating to other kinds of shares.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except:

- (1) with the approval of a special resolution of the holders of the relevant class at a separate meeting;
- (2) with the consent in writing of the holders of at least three-fourths of the total voting rights of holders of shares in the class in question;
- (3) by agreement of all the members of a Hong Kong company; or
- (4) 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 Company Law, unlike the Companies Ordinance, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on directors’ authority in making major dispositions, 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.

Supervisory Committee

Under the Company Law, a joint stock limited company’s directors and senior management are subject to the supervision of a supervisory committee. There is no mandatory requirement for the establishment of a supervisory committee for a company incorporated in Hong Kong.

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Derivative Action by Minority Shareholders

Hong Kong law permits minority shareholders to initiate a derivative action on behalf of all shareholders against directors who have committed a breach of their fiduciary duties 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.

Under the Company Law, if the directors and senior management of a joint stock limited company violate laws, administrative regulations or its articles of association, resulting in losses to the company, shareholders individually or jointly holding over 1% of the shares in the company for more than 180 consecutive days may request in writing the supervisory committee to initiate proceedings in the people’s court. If the supervisors violate the relevant provisions of the Company Law, the above shareholders may request in writing the board of directors to initiate litigation at the people’s court. Upon receipt of such written request from the shareholders, if the supervisory committee or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon 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.

Protection of Minorities

Under Hong Kong law, a shareholder who complains that the affairs of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to court to either wind up the company or make an appropriate order regulating the affairs of the company. In addition, on the application of a specified number of members, the Financial Secretary of Hong Kong may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated in Hong Kong.

The Company Law provides that any shareholders holding 10% or more of the voting rights of all issued shares of a company may request a People’s Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and the company continues to suffer serious losses and no other alternatives can resolve.

Financial Disclosure

Under the 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’ general meeting. In addition, a joint stock limited company of which the public offering Shares are offered must publish its financial report. The Hong Kong law requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial report, auditors’ report and directors’ report, which are to be presented before the company in its annual general meeting, not less than 21 days before such meeting.

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Under the Company Law, a company shall at the end of each accounting year prepare a financial report which shall be audited by the accounting firm in accordance with the laws.

Information on Directors and Shareholders

The Company Law gives shareholders the right to inspect the articles of association, minutes of the shareholders’ general meetings and financial and accounting reports. Under the articles of association, shareholders have the right to inspect and copy (at reasonable fee) certain information on shareholders and on directors similar to that available to shareholders of Hong Kong companies under the Companies Ordinance.

Receiving Agents

Under the Company Law and Hong Kong law, dividends once declared are debts payable to shareholders. Under Hong Kong law, the limitation period for an action to demand repayment of a debt is six years, whereas the PRC Civil Code (《中華人民共和國民法典》) provides that the limitation period for an action to be taken is three years.

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 members pursuant to Division 2 of Part 13 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 the Company Law, the merger, demerger, dissolution or change to the forms of a joint stock limited company has to be approved by shareholders in shareholders’ general meeting.

Statutory Deductions

Under the Company Law, a company shall draw 10% of the profits as its statutory reserve fund before it distributes any profits after taxation. When the aggregate amount of the company’s statutory reserve fund reaches 50% of the company’s registered capital, the company may no longer make allocations from the statutory reserve fund. After a company has made an allocation to its statutory reserve fund from its after-tax profit, it may make an allocation to its discretionary reserve fund from its after-tax profit upon a resolution approved at the shareholders’ general meeting. There are no such requirements under Hong Kong law.

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Remedies of Company

Under the 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.

The Listing Rules require listed companies’ articles of association to provide for remedies of the company (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management) similar to those available under Hong Kong law.

Dividend

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder.

Under Hong Kong law, 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. The company shall 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, there is the common law concept of the fiduciary duty of directors, 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 Company Law, directors, supervisors, managers and other senior management personnel of a company have the duty of loyalty and diligence to the company. Such persons shall abide by the articles of association of the company, perform their duties faithfully, safeguard the interests of the company, and shall not use their position and authority in the company for their personal gain.

Closure of Register of Members

The Companies Ordinance requires that the register of shareholders of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days in certain circumstances) in a year, whereas, as required by the Company Law, 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.

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SUMMARY OF ARTICLES OF ASSOCIATION

This Appendix sets out summaries of the main clauses of our Articles of Association adopted on June 2, 2023, which shall become effective as at the date on which will be effective from the date of [REDACTED] of H Shares on the Hong Kong Stock Exchange. This appendix is primarily intended to provide potential investors with an overview of the Company’s Articles of Association and therefore may not contain all the information that is material to potential investors.

1 DIRECTORS AND BOARD OF DIRECTORS

(1) Power to allocate and issue shares

The Articles of Association does not contain clauses that authorize the Board of Directors to allocate or issue shares. The Board of Directors shall prepare suggestions for share allotment or issue, which are subject to approval by the Shareholders at the general Shareholders’ meeting in the form of a special resolution. Any such allotment or issue shall be in accordance with the procedures stipulated in appropriate laws, administrative regulations and supervision rules of shares [REDACTED] region.

(2) Power to dispose of assets of our Company or any subsidiary

The Board of Directors shall determine the authority of external investment, acquisition and sale of assets, asset mortgage, external guarantee matters, entrusted financial management, connected transactions, external donations, and establish strict review and decision-making procedures; major investment projects shall be reviewed by relevant experts and professionals and reported to the shareholders’ meeting for approval.

The transaction within the scope of daily business of the Company that meets one of the following criteria shall be submitted to Board of Directors for deliberation:

- i. The transaction amount accounts for more than 50% of the Company’s audited total assets in the latest period, and the absolute amount exceeds RMB100 million;
- ii. The transaction amount accounts for more than 50% of the Company’s audited operating income or operating cost in the latest accounting year, and more than RMB100 million;
- iii. The total profit expected from the transaction accounts for more than 50% of the audited net profit of the Company in the latest accounting year, and more than RMB5 million;
- iv. Transactions that should be submitted to the Board of Directors for deliberation in accordance with the relevant provisions of the Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED];
- v. Other transactions that may have a significant impact on the Company’s assets, liabilities, equity and operating results.

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(3) Guarantees to Directors, Supervisors or other management personnel

The following acts of external guarantee of the Company shall be submitted to the General Meeting for deliberation and approval after being reviewed and approved by the Board of Directors:

- i. Any guarantee to be provided after the total amount of external guarantees provided by the Company or the subsidiaries it controls has exceeded 50% of the Company’s net assets as audited in the latest period;
- ii. Any guarantee to be provided after the total amount of external guarantees provided by the Company has exceeded 30% of its total assets as audited in the latest period;
- iii. The amount guaranteed by the Company within one year exceeds 30% of its latest audited total assets;
- iv. Any guarantee to be provided for a party whose ratio of liabilities to assets exceeds 70%;
- v. Any single guarantee for an amount more than 10% of the Company’s net assets audited in the latest period;
- vi. Any guarantee to be provided to a Shareholder, or to an ultimate controller or related party thereof;
- vii. Other external guarantees that meet the requirements of laws, regulations, normative documents the Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED] can take effect only after being reviewed and approved by the General Meeting.

(4) Provide financial assistance for acquiring the shares of the Company or shares of any subsidiary

The Company or its subsidiaries (including its subsidiaries) will not provide any financial assistance to the person who purchases or intends to purchase the company’s shares in the form of gifts, advances, guarantees, compensation or loans.

(5) Remuneration

The appointment and removal of the members of the Board of Directors and the Board of Supervisors, as well as their remuneration and payment methods, shall be adopted by the general shareholders’ meeting by ordinary resolution.

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SUMMARY OF ARTICLES OF ASSOCIATION

(6) Appointment, Resignation and Dismissal

The Board of Directors consists of fourteen Directors, at least five of whom are independent non-executive Directors. The Board of Directors has one chairman. Directors are elected at the general Shareholders' meeting.

The chairman of the Board shall be elected and dismissed by a vote of more than one half of the Directors. The chairman of the Board serves 3-year term and other Directors serve 3-year term. Upon expiration of the term, the Director may be re-elected. Director can be the general manager or other senior management personnel at the same time. However, the number of the Directors who are also general manager or other senior management personnel shall not be more than half of the total number of Directors. There is no provision in the Articles of Association that imposes any age limit for Directors beyond which retirement of a Director is mandatory.

None of the following persons shall serve as our Director, Supervisor or senior management:

- i. A person who has no civil capacity or has limited civil capacity;
- ii. A person who has been imposed penalty for the offense of corruption, bribery, embezzlement, larceny, or disrupting the social economic order and is within five years of the expiry date of punishment or has been deprived of political rights because of this conviction and is within five years of the expiry date of the sentence;
- iii. A person who is a former director, factory manager or general manager of a company or enterprise that is bankrupt and liquidated because of poor operation, was personally liable for the bankruptcy of such company or enterprise, and is within three years of the date of completion of bankruptcy and liquidation of such company or enterprise;
- iv. A person who has served as the legal representative of a company or enterprise whose business license was revoked or was ordered to close due to violation of laws, was personally liable, and is within three years of the date on which the business license of such company or enterprise was revoked;
- v. A person who has a relatively large sum of debt, which was not paid at maturity;
- vi. A person who has been banned from entering the securities market by the CSRC and whose term has not expired;
- vii. A person who has been subject to administrative punishment by the CSRC in the last three years, or has been publicly denounced by the stock exchange in the last 12 months;

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- viii. A person who has been filed for investigation by the judicial authority due to suspected crimes or has been filed for investigation by the CSRC due to suspected violations of laws and regulations, and has not yet reached a clear conclusion;
- ix. Other contents stipulated by laws, administrative regulations, departmental rules, other normative documents, the Listing Rules and other securities regulatory rules of the place where the company's shares are [REDACTED].

The election, appointment or employment of the Directors, Supervisors or other senior management shall be invalid if such election, appointment or employment is against the Articles of Association. If the Directors, Supervisors or senior management fall into the situations provided in the above-mentioned situations during their term of office, they would be dismissed by our Company.

(7) Duties

The directors shall abide by laws, administrative regulations and the Articles of Association, and shall have the following fiduciary duties to the Company:

- i. Shall not abuse their authority by accepting bribes or other illegal income, and shall not convert company property;
- ii. Shall not misappropriate company funds;
- iii. Shall not deposit Company's assets into accounts held in their own names or in the name of any other individual;
- iv. Shall not, in violation of the Articles of Association, loan Company's funds to any other person or give Company's assets as security for the debt of any other person without the approval of the General Meeting or the Board of Directors;
- v. Shall not conclude any contract or engage in any transaction with the Company either in violation of the Articles of Association or without the approval of the General Meeting;
- vi. Shall not use the advantages provided by their own positions to pursue business opportunities that properly belong to the Company to engage in the same business as the Company either for their own account or for the account of any other person without the approval of the General Meeting;
- vii. Shall not accept commissions for transactions conducted with the Company as their own;
- viii. Shall not disclose confidential Company's information without authorization;

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- ix. Shall not abuse their connected relationships to damage the Company's interests;
- x. Laws, administrative regulations, departmental rules, the Listing Rules, other securities regulatory rules of the place where the company's shares are [REDACTED] and other fiduciary obligations stipulated in the Articles of Association.

The income obtained by the director in violation of above article shall belong to the Company. If losses are caused to the Company, it shall be liable for compensation.

Directors shall abide by laws, administrative regulations and the Articles of Association, and have the following diligent obligations to the Company:

- i. Shall prudently, earnestly and diligently exercise the powers the Company grants to them to ensure that the Company conducts its commercial activities in a manner that complies with the requirements of state laws, administrative regulations and state economic policies, and that the Company's commercial activities do not go beyond the scope of the business activities stipulated in the Company's business license;
- ii. Shall treat all Shareholders fairly;
- iii. Shall maintain a timely awareness of the operation and management of the Company;
- iv. Shall sign written statements confirming the regular reports of the Company, and ensure that the information disclosed by the Company is true, accurate and complete;
- v. Shall provide accurate information and materials to the Board of Supervisors and shall not obstruct the Board of Supervisors or individual Supervisors from performing its or their duties;
- vi. Laws, administrative regulations, departmental rules, the Listing Rules, other securities regulatory rules of the place where the Company's Shares are [REDACTED], and other obligations of diligence stipulated in the Articles of Association.

The duty of loyalty assumed by the Directors shall not be automatically relieved within a reasonable period after the resignation report has not come into effect or has come into effect, and within a reasonable period after the end of the term of office. The duty of confidentiality of the Company's business secrets shall remain valid after the resignation report comes into effect or the end of the term of office, until the secrets become public information.

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The specific time limit for Directors to undertake the obligation of loyalty after the resignation takes effect or the term of office expires is 2 years from the date of the resignation takes effect or the term of office expires. The duration of other obligations shall be determined in accordance with the principle of fairness, depending on the length of time between the occurrence of the event and the departure of the post, and the circumstances and conditions under which the relationship with the Company ends.

Without the provisions of the Articles of Association or the lawful authorization of the Board of Directors, no Director shall act in his own name on behalf of the Company or the Board of Directors. When a Director acts in his/her own name, the Director shall declare his/her position and identity in advance if the third party reasonably believes that the Director is acting on behalf of the Company or the Board of Directors.

In the event of any loss caused to our Company as a result of violation of any laws, administrative regulations or Articles of Association by the Directors or senior management when performing their duties in our Company, the Shareholders holding 1% or more shares separately or jointly for over 180 consecutive days may submit a written request to the Board of Supervisors to file an action with the people's court. Where supervisors violate laws, administrative regulations or the Articles of Association in their duty performance and cause loss to our Company, the Shareholders may submit a written request to the Board of Directors to file an action with the people's court.

In the event that the Board of Supervisors or the Board of Directors refuse to file an action upon receipt of the Shareholders' written request specified in the preceding paragraph, or fail to file an action within 30 days upon receipt thereof, or in the event that the failure to immediately file an action in an emergency case will cause irreparable damage to the interests of our Company, the Shareholder(s) specified in the preceding paragraph may, in their own name, directly file an action to the court for the interest of our Company.

In the event of any other person infringes upon the legitimate rights and interests of our Company and causes losses thereto, the Shareholder(s) specified in this Articles of Association may file an action with the competent court pursuant to the provisions of the preceding two paragraphs.

In the event of a Director or senior management person violates laws, administrative regulations or our Company's Articles of Association, thereby damaging the interests of the Shareholder(s), the Shareholder(s) may file an action with the competent court.

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2 MODIFICATION OF THE ARTICLES OF ASSOCIATION

Our Company may amend the Articles of Association based on the provisions of the laws, administrative regulations and the Articles of Association.

Where the amendments to the Articles of Association passed by the general Shareholders’ meetings need the examination and approval of the competent authorities, these amendments shall be submitted hereto for approval. Where the amendment of the Articles of Association involves registration, it shall be necessary to carry out the lawfully prescribed procedures for registration change.

3 SPECIAL RESOLUTIONS NEEDED TO BE ADOPTED BY ABSOLUTE MAJORITY VOTE

The resolutions of the Shareholders’ meeting shall be divided into ordinary resolutions and special resolutions.

An ordinary resolution may be adopted by a simple majority of the votes held by the Shareholders (including proxies of Shareholders) attending the general Shareholders’ meeting.

A special resolution can be adopted by a two-thirds majority of the votes held by the Shareholders (including proxies of Shareholders) attending the general Shareholders’ meeting.

4 VOTING RIGHTS

The Shares held by the Shareholders of the Company are ordinary shares, without special voting rights. Shareholders (including proxy) shall exercise their voting rights according to the number of voting Shares they represent, and each Share shall have one vote.

When voting at the general Shareholders’ meeting, the Shareholder (including proxy) may exercise his or her voting rights in accordance with the number of shares with voting power held with each share representing one vote.

Any Shareholder who is required by the Hong Kong Listing Rules to abstain from voting on a matter or is limited to an affirmative or negative vote shall abstain from voting or be required to so vote; any vote cast by or on behalf of relevant shareholder which is cast in violation of such requirement or restriction shall not be counted in the voting result.

The shares held by the Company itself shall have no voting right and shall not be counted in the total number of voting shares at the shareholders’ meeting.

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5 RULES ON GENERAL SHAREHOLDERS’ MEETINGS

The general Shareholders’ meetings are divided into annual general Shareholders’ meetings and extraordinary general Shareholders’ meetings. The annual general shareholders’ meeting shall be convened once a year and be held within six months of the end of the previous fiscal year.

At the time of the General Meeting of Shareholders, all shareholders or their proxies who are registered in the Register of Shareholders on the Date of The Share Registration are entitled to attend the meeting, to speak at the meeting and to exercise their voting rights in accordance with the relevant laws, rules and the Articles of Association.

6 ACCOUNTING AND AUDITS

(1) Financial and accounting policies

Our Company shall develop its financial accounting policies pursuant to laws, administrative regulations and rules developed by the competent department. Where there are special rules in the listing rules of the stock exchange where the shares are [REDACTED], the special rules would prevail.

The Company shall prepare its annual financial and accounting report within 4 months after the end of each fiscal year, and prepare its interim financial and accounting report within 2 months after the end of the first half of each fiscal year. The above financial and accounting reports are prepared in accordance with relevant laws, administrative regulations, departmental rules, the Listing Rules and other securities regulatory rules of the place where the Company’s Shares are [REDACTED].

The Company shall not establish other accounting books except for the statutory accounting books. The assets of the Company shall not be deposited in any account opened in the name of any individual.

(2) Appointment and Dismissal of Accountants

The Company employs an accounting firm that complies with the provisions of the Securities Law, the Listing Rules and other securities regulatory rules of the place where the Company’s Shares are [REDACTED] to conduct accounting statement audit, net asset verification and other related consulting services. The employment period is one year, and can be renewed.

The employment of accounting firms by the Company must be decided by the general shareholders’ meeting, and the Board of Directors shall not appoint accounting firms before the decision of the general shareholders’ meeting. The audit fee of the accounting firm shall be determined by the general shareholders’ meeting.

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The Company shall guarantee to provide the accounting firm it employs with true and complete accounting vouchers, accounting books, financial and accounting reports and other accounting materials, and shall not refuse, conceal or make false statements.

The Company shall notify the accounting firm 15 days in advance when dismissing or no longer renewing the accounting firm. The accounting firm shall be allowed to state its opinions when the general shareholders' meeting votes on dismissing the accounting firm. If the accounting firm proposes to resign, it shall explain to the general shareholders' meeting whether the Company has any improper situation.

7 NOTICE AND AGENDA OF GENERAL SHAREHOLDERS' MEETINGS

The general Shareholders' meeting is the authorized organ of our Company that performs duties and exercises powers in accordance with the law.

Under any of the following circumstances, our Company shall convene an extraordinary general Shareholders' meeting within two months:

- i. The number of Directors is less than the minimum number specified in the PRC Company Law or less than two thirds of the number required in the Articles of Association;
- ii. The uncovered losses of our Company reach one-third of its total paid-in share capital;
- iii. The Shareholders with 10% or more shares of the Company separately or jointly request to convene an extraordinary general Shareholders' meeting in writing (the shareholding ratio shall be calculated by the day of the request);
- iv. The Board of Directors considers it necessary;
- v. The Board of Supervisors considers it necessary;
- vi. Any other circumstances stipulated in laws, administrative regulations, regulations of the authorities, the Listing Rules and other securities regulatory rules of the place where the Company's Shares are [REDACTED] or the Articles of Association.

In the event that the Board of Directors agrees to convene an extraordinary general Shareholder's meeting, the notice of convening extraordinary general Shareholder's meeting shall be issued within 5 days after the Board of Directors makes a resolution. With regard to the proposal of convening an extraordinary general meeting made by the Board of Supervisors, if the Board of Directors made a rejection or does not respond within 10 days after it receiving the proposal, it shall be viewed as the Board of Directors is unable to or fails to perform its meeting duty of convening the General Shareholder's Meeting and the Board of Supervisors may convene and preside over the meeting by its own.

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Shareholders who separately or jointly hold 10% or more of the shares may request in writing to convene an extraordinary general Shareholder’s meeting. If the Board of Directors does not issue a notice of convening the meeting within 10 days after receiving the above written requirement, or refused to convene, the shareholders who make the request may request the Board of Supervisors in writing to convene the meeting.

If the Board of Supervisors does not issue the notice about convening the meeting within 5 days after receiving the above written requirement, the shareholders holding 10% or more shares separately or jointly for over 90 consecutive days could convene and preside the meeting by themselves.

In the event that the general shareholders’ meeting is convened, the Board of Directors, the Board of Supervisors and shareholders who separately or jointly hold more than 3% of the shares of our Company may submit a proposal 10 days before the meeting.

When convening a general shareholders’ meeting, our Company shall send a written notice 20 business days before it is convened. When convening an extraordinary shareholders’ meeting, our Company shall send a written notice 15 days before it is convened. When the Company calculates the starting period of “20 business days” and “15 days”, it does not include the date of the meeting, but includes the date of the notice.

The notice of the general shareholders’ meeting shall be made in writing, including the following contents:

- i. the place, the date and the hour of the meeting;
- ii. the matters to be discussed at the meeting;
- iii. conspicuous statement that all common shareholders (including preferred shareholders whose voting rights have been restored) are entitled to attend the meeting and appoint proxy to attend and vote and that proxy need not be a shareholder;
- iv. the registration date of the share of the shareholder entitled to attend the Shareholders’ meeting;
- v. name and phone number of the standing contact person for affairs;
- vi. voting time and voting procedure by network or other means (if any);
- vii. information and explanations necessary for the shareholders to exercise an informed judgment on the proposals before them. It principally includes (but is not limited to), where a proposal is made to amalgamate the Company, to repurchase shares, to

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reorganize the share capital or to restructure our Company in any other way, the conditions of the proposed transaction must be provided in detail together with the proposed contract (if any), and the cause and consequence of such proposal must be properly explained;

- viii. disclosure of the nature and extent, if any, of the material interests of any Director, Supervisor, senior management in the matter to be discussed and the effect of the proposed matter on such Director, Supervisor, Manager or other senior management in their capacity as shareholders in so far as it is different from the effect on the interests of the shareholders of the same class;
- ix. the full text of any special resolution proposed to be voted at the meeting;
- x. the delivery date and place lodging proxy forms;
- xi. other requirements specified in the laws, administrative regulations, regulations of the authorities, the Listing Rules and other securities regulatory rules of the place where the shares are [REDACTED] and the Articles of Association, etc.

The notice of the general shareholders’ meeting and the supplementary notice shall fully and completely disclose all the specific contents of all proposals, as well as all the materials or explanations required to enable the Shareholders to make a reasonable judgment on the matters to be discussed. If the matter to be discussed needs the opinion of independent Directors, the opinions and reasons of independent Directors will be disclosed at the same time when the notice general shareholders’ meeting or supplementary notice is issued. The start time of voting (if any) by network or other means at the general shareholders’ meeting shall not be earlier than 3:00 p.m. on the day before the on-site general shareholders’ meeting is held, nor later than 9:30 a.m. on the day of the on-site general shareholders’ meeting, and the end time shall not be earlier than 3:00 p.m. on the day of the on-site general shareholders’ meeting.

The interval between the equity registration date and the meeting date shall be no more than 7 working days. Once the equity registration date is confirmed, it cannot be changed.

The resolution of the general shareholders’ meeting includes ordinary resolution and special resolution. The following matters shall be approved by the general shareholders’ meeting through ordinary resolutions:

- i. Work report of the Board of Directors and the Board of Supervisors;
- ii. Plans of earnings distribution and loss make-up schemes drafted by the Board of Directors;
- iii. Appointment or dismissal of the members of the Board of Directors and the Board of Supervisors, and their payment and payment methods;

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- iv. Annual budgets plan, final accounts plan of the Company;
- v. Annual report of the Company;
- vi. To decide the Management policy and investment plan of the Company;
- vii. To engage or dismiss the accounting firm;
- viii. Other matters other than those approved by special resolution stipulated in the laws, administrative regulations, the Listing Rules and other securities regulatory rules of the place where the shares are [REDACTED] or the Articles of Association.

The following matters shall be approved by special resolution at the general shareholders’ meeting:

- i. The increase or decrease of the share capital, or the issuance of stock, warrants or other quasi-securities;
- ii. Issuance of company bond;
- iii. Division, merger, the change of form of our Company, dissolution and liquidation of our Company;
- iv. Amendment or supplement of the Articles of Association;
- v. The Company’s purchase, sale of significant assets or the amount of guarantee within one year have exceeded 30% of its total assets as audited in the latest period;
- vi. Equity incentive plan;
- vi. Other matters as required by the laws, legal rules, administrative regulations, the Listing Rules and other securities regulatory rules of the place where the shares are [REDACTED] and the Articles of Association, and as approved by ordinary resolution of the general shareholders’ meeting which are believed could materially affect our Company and need to be approved by special resolution.

In the event that any resolution of the general Shareholders’ meeting or resolution of the Board of Directors violates laws or administrative regulations, any shareholder is entitled to request the court to deem it as invalid.

In the event that the convening procedure or voting formula of the shareholders meeting or meeting of the Board of Directors violates any of laws, administrative regulations or the Articles of Association, or resolution of which violates the Articles of Association, any shareholder is entitled to ask the court to overturn within 60 days after the resolution was adopted.

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8 SHARE TRANSFERS

The shares of our Company holding by the funders thereof shall not be transferred within one year of the date of establishment of our Company. The shares issued before the public issuance of shares by our Company shall not be transferred within one year of the date on which the stocks of our Company are [REDACTED] and traded on a securities exchange.

The Directors, Supervisors, and senior management of our Company shall declare, to our Company, information on their holdings of the shares of our Company and the changes thereto. The shares transferable by them during each year of their term of office shall not exceed 25 percent of their total holdings of the shares of our Company. The shares that they held in our Company shall not be transferred within one year of the date on which the stocks of our Company are [REDACTED] and traded. The aforesaid persons shall not transfer their shares of our Company within six months from the date of their resignation.

Where any Director, Supervisor or senior manager of the Company who holds more than 5% of the Company Shares sells company's stock he holds within 6 months of the relevant purchase, or purchases any stock he has sold within 6 months of the relevant sale, the proceeds generated therefrom shall be incorporated into the profits of the Company, and the Board of Directors of the Company shall recover the proceeds. However, the following circumstances shall be excluded where a securities company holds more than 5% of the shares due to its purchase of any remaining Shares under a best efforts underwriting or where the provisions of the securities regulatory authority under the State Council and the securities regulatory authority at the place where the Shares of the Company are [REDACTED] apply.

Shares or other securities with the nature of equity held by Directors, Supervisors, senior executives and individual shareholders as mentioned in the preceding paragraph include shares or other securities with the nature of equity held by their spouses, parents or children, or held by them by using other people's accounts. If the Board of Directors of the Company fails to comply with the above paragraph of this Article, the Shareholders are entitled to request the Board of Directors to do so within 30 days. If the Board of Directors of the Company fails to comply within the aforesaid period, the Shareholders are entitled to initiate litigation directly in the People's Court in their own names for the interest of the Company. And if the Board of Directors fails to implement the provisions set forth in this Article, the responsible Directors shall bear joint and several liability in accordance with law.

9 RIGHTS OF OUR COMPANY TO PURCHASE OUR OUTSTANDING ISSUED SHARES

Under any of the following circumstances, our Company may submit to relevant competent authorities for approval to buy back our outstanding issued shares according to legal procedures with the approval of procedures stipulated in the Articles of Association:

- i. Reduce our Company's registered capital;

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- ii. Merger with other companies which hold our shares;
- iii. Granting shares to the staff of our Company as incentives;
- iv. Requesting the Company to buy back its shares from shareholders who vote against any resolutions adopted at the general shareholders’ meeting concerning the merger and division of the Company;
- v. To convert shares into bond issued by our Company which is convertible to stock of our Company;
- vi. Necessary for our Company to maintain our Company’s value and Shareholders’ equity.

A Company may purchase its own Shares through public centralized trading, or through other means recognized by the laws, administrative regulations, the Listing Rules, and other securities regulatory rules of the place where the Company’s Shares are [REDACTED] or the CSRC (if required). Where any Company purchases its own Shares under any of the circumstances specified in Items 3, 5, or 6 of Article 25 of its Articles of Association, centralized trading shall be adopted publicly.

Upon buyback of the Company’s Shares, the Company shall perform information disclosure obligation pursuant to the relevant provisions of laws, administrative regulations, rules, normative documents and the Listing Rules etc. Where the relevant regulatory rules of the place where the Company’s Shares are [REDACTED] stipulate otherwise on matters involved in Share buyback, such provisions shall prevail.

The contract that buys back the shares includes (but is not limited to) an agreement that consents to undertake the obligation to buy back the shares and obtain the rights to buy them back.

10 POWERS FOR ANY SUBSIDIARY OF OUR COMPANY TO OWN SHARES IN ITS PARENT

There are no provisions in the Articles of Association relating to ownership by subsidiary of our Company of shares in its parent.

11 DIVIDEND AND OTHER DISTRIBUTION METHODS

The Company attaches importance to the reasonable return on investment to Shareholders, and the profit distribution should follow the principle of paying attention to the reasonable return on investment to Shareholders and benefiting the long-term development of the Company. The Company’s profit distribution policy should maintain continuity and stability, and comply with the relevant provisions of laws and regulations. The Company may

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distribute dividends in cash or stock. Under the condition that the Company has distributable profits, the Board of Directors of the Company may make cash dividend distribution plans or/and stock dividend distribution plans according to the Company's business and financial conditions.

After the shareholders' meeting of our Company makes a resolution on dividends distribution plan, the Board of Directors shall complete the distribution within 2 months after the convening of the shareholders' meeting.

12 SHAREHOLDER PROXIES

Any shareholder who is entitled to attend and vote at general shareholders' meeting has the right to appoint one or more persons (who may not necessarily be shareholders) as his or her shareholder proxy to attend and vote at the meeting in his or her place. Pursuant to the authorization of the shareholder, the proxy may exercise the following rights:

- i. Speak for the shareholder at the general shareholders' meeting;
- ii. Demand a poll individually or with others;

The power of attorney shall indicate whether the shareholder's proxy can vote according to his own will if the Shareholder does not give specific instructions. A Shareholder's proxy need not be a Shareholder of the Company.

Where a Shareholder authorizes another person to sign a proxy statement for voting, the power of attorney for signing authority or other authorization documents shall be notarized. The notarized power of attorney or other authorization documents shall be lodged at the Company's domicile or any other place stipulated in the meeting notice. Where the Shareholder is a legal person, its legal representative or any person authorized by a resolution of the Board of Directors or other decision-making body shall attend the general shareholders' meeting as its proxy.

If the principal shareholder is a Recognized Clearing House (or his agent) as defined in the relevant ordinances enacted from time to time in Hong Kong, the shareholder may authorize its company representative or one or more persons as it deems appropriate to act as its representative at any general meeting of shareholders or any class of shareholders. However, if more than one person is authorized, the power of attorney or letter of authorization shall specify the number and type of shares involved in such authorization, and the power of attorney shall be signed by the authorized person of the recognized clearing house. Such authorized person may represent the Recognized Clearing House (or its proxies) at the meeting (without presenting a shareholding certificate, notarized authorization and/or further evidence confirming its duly authorization) exercising the statutory rights equivalent to those enjoyed by other shareholders, including the right to speak and vote, as if the person were an individual shareholder of our Company.

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13 REVIEW THE REGISTER OF SHAREHOLDERS AND OTHER RIGHTS OF SHAREHOLDERS

Our Company shall make a register of shareholders in accordance with evidentiary documents provided by the securities registration authorities.

The register of Shareholders is sufficient evidence to prove that the Shareholders hold the Company’s Shares. Shareholders enjoy rights and assume obligations according to the types of shares they hold. Shareholders holding the same kind of Shares shall enjoy the same rights and undertake the same obligations.

Our Company shall keep a copy of the register of the shareholders of the overseas [REDACTED] foreign shares at our residential address. The overseas entrusted agency shall at all times maintain consistency between the original and copy of the register of the shareholders of the overseas [REDACTED] foreign shares. The register of shareholders maintained in Hong Kong must be accessible to shareholders, but a company may be allowed to suspend the registration of shareholders under the same terms as the Company Ordinance (Cap. 622).

14 RESTRICTIONS ON RIGHTS OF CONTROLLING SHAREHOLDERS

The controlling Shareholders and actual controllers of the Company shall not use their connected relationship to damage the legitimate interests of the Company and other shareholders; Controlling shareholders and actual controllers who violate relevant laws, regulations and Articles of Association and cause losses to the Company and other Shareholders shall be liable for compensation.

Controlling Shareholders and ultimate controllers of the Company shall have a duty of care to the Company and other Shareholders. Controlling Shareholders shall exercise their investors’ rights in strict accordance with the law and shall not damage the lawful interests of the Company or of public Shareholders in any way such as via the distribution of profits, an asset reorganization, external investments, the use of Company’s funds or the provision of a loan guarantee, nor shall they abuse their controlling positions to damage the interests of the Company or of public Shareholders.

15 PROCEDURES FOR LIQUIDATION

Under any of the following circumstances, our Company shall be lawfully dissolved and liquidated:

- i. The term of business of our Company has expired or other circumstances that may lead to the liquidation of our Company as stipulated in the Article of Association;
- ii. The general shareholders’ meeting adopts a resolution to dissolve our Company;
- iii. Our Company needs to be dissolved for the purpose of merger or division;

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- iv. The business license is revoked, or our Company is ordered to close or be eliminated according to applicable law;
- v. Where our Company encounters significant difficulties in business and management, continuous survival may be significantly detrimental to the interests of the shareholders, and the difficulties may not be overcome through other means, shareholders who hold more than 10% of all voting rights of the Company's shareholders may request the People's Court to dissolve the Company.

Where our Company is dissolved due to the provisions set forth in i, ii, iv and v above, the liquidation team shall be established within 15 days from the date of the event leading to liquidation to commence dissolution and the personnel of the liquidation team shall consist of the persons determined by the Directors or the general shareholders' meeting. In the event the liquidation team is not established to conduct liquidation during such period, the creditors can request the people's court to appoint relevant personnel to establish the liquidation team for liquidation.

Within 10 days of the establishment of the liquidation team, the creditors shall be notified and an announcement shall be published in the newspaper within 60 days. The creditors shall declare their claims to the liquidation team within 30 days of the date on which the notice is received or 45 days of the date of announcement if the notice is not received.

Creditors who declare claims shall state relevant issues related to the claims and provide proofs. The liquidation team shall carry out registration of the claims. During the period for declaration of claims, the liquidation group shall not make any repayment to the creditors.

During the liquidation, our Company shall continue to exist, but shall not carry out business activities irrelevant to the liquidation. The property of our Company shall not be distributed to any shareholder before full payments have been made from the property according to the aforesaid provision.

Upon liquidation for the purpose of company dissolution, in the event the liquidation team finds that, after taking stock of our Company's property and preparing the balance sheet and list of property, that the assets are insufficient to pay the debts, it shall immediately apply to the people's court to declare bankruptcy.

After our Company is declared bankrupt by ruling of the people's court, the liquidation team shall turn over matters regarding the liquidation to the people's court.

16 OTHER IMPORTANT PROVISIONS FOR OUR COMPANY OR THE SHAREHOLDERS

(1) General Provisions

Our Company is a permanently existing joint stock limited company.

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(2) Share and Transfer

Our Company may increase stock capital by the following means:

- i. Issuing new shares to unspecified investors;
- ii. Placing new shares to specified investors;
- iii. Allocating or giving new shares to existing shareholders;
- iv. Converting the reserve funds into share capital;
- v. Other means approved by the laws, administrative regulations, CSRC and Hong Kong Stock Exchange.

Our Company may decrease our registered share capital and shall comply with the procedures stipulated in Company Law of the PRC, the Listing Rules, other securities regulatory rules of the place where the shares are [REDACTED] and the Articles of Association.

Upon approval by the competent securities department of the State Council, our Company may issue shares to overseas investors.

For the purpose of the preceding paragraph, overseas investors shall refer to investors from foreign countries and Hong Kong, Macao or Taiwan region who subscribe for shares issued by our Company.

Where permitted by the laws, administrative regulations and regulations of authorities, upon approval and filed by the competent securities department of the State Council and approved by the Hong Kong Stock Exchange, the not [REDACTED] shares of the Company can be [REDACTED] and traded on an overseas stock exchange. Such domestic shares shall be in compliance with the regulatory procedures, provisions and requirements of overseas securities market after being [REDACTED] and traded on an overseas stock exchange.

Domestic [REDACTED] Shares and overseas [REDACTED] foreign Shares issued by the Company enjoy the same rights in any distribution made in the form of dividends (including cash and physical distribution) or other forms. It is not allowed to exercise any power to freeze or otherwise damage any of its rights attached to the shares just because any person who directly or indirectly owns the interests has not disclosed their interests to the company.

Domestic [REDACTED] shares are converted into overseas [REDACTED] shares and [REDACTED] for trading on overseas stock exchanges, and there is no need to convene a general meeting of shareholders to vote.

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(3) Shareholders

The shareholders of our Company are persons lawfully holding the Company’s shares and whose names (titles) are already [REDACTED] in the register of shareholders. Shareholder is entitled to rights and assumes obligations pursuant to the classification and ratio of his or her shares. Shareholder holding the same classified share has the same rights and assumes the same obligations.

The rights of our shareholders are as follows:

- i. To receive distribution of dividends and other forms of benefits according to the number of shares held;
- ii. To legally require, convene, preside over, participate in or authorize proxies of Shareholders to attend the general shareholder’s meeting and exercise corresponding voting rights;
- iii. To supervise and manage business and operational activities of our Company, provide suggestions or submit queries;
- iv. To transfer, grant and pledge the Company’s shares held according to the provisions of the laws, administrative regulations, regulations of authorities, normative documents of the PRC and Listing Rules on Stock Exchanges and the Articles of Association;
- v. To read the Articles of Association, the list of Shareholders, Company bond stubs, General Shareholders’ Meeting minutes, resolutions of meetings of the Board of Directors, resolution of meetings of the Board of Supervisors and financial and accounting reports;
- vi. To participate in the distribution of the remaining assets of our Company according to the proportion of shares held upon our termination or liquidation;
- vii. To require our Company to acquire the shares from Shareholders voting against any resolutions adopted at the general Shareholders’ meeting concerning the merger and division of the Company;
- viii. Shareholders who individually or collectively hold more than 3% of the company’s shares have the right to put forward a temporary proposal and submit it to the convener in writing 10 working days before the shareholders’ meeting;
- ix. Other rights conferred by laws, administrative regulations, regulations of the authorities, the Listing Rules, regulatory rules where our Company’s shares are [REDACTED], or the Articles of Association.

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(4) The Board of Directors

The Board of Directors is responsible to the general Shareholders’ meeting and exercises the following powers:

- i. To convene the general Shareholders’ meeting and report on work to the general Shareholders’ meeting;
- ii. Implement the resolutions of the general Shareholders’ meeting;
- iii. Determine the business and investment plans of our Company;
- iv. Devise the annual financial budget and closing account plans of our Company;
- v. Devise the earnings distribution and loss offset plans of our Company;
- vi. Adjust profit distribution policy;
- vii. Formulate the plans for increasing or decreasing our Company’s registered capital, the issuance of corporate bonds or other securities, as well as the [REDACTED] of the stock of our Company;
- viii. Formulate plans for major acquisitions of the Company, the buy-back of shares of our Company, corporate merger, separation of our Company, changing the form and dissolution of our Company;
- ix. Determine such matters as the Company’s external investment, purchase or sale of assets, asset pledge, external guarantee, entrusting wealth management connected transaction and external donations within the scope authorized by the general Shareholders’ meeting;
- x. Investments, acquisitions or disposals of assets, financing, connected transactions (other than transactions between the Company and its subsidiaries) that require decisions by the Board of Directors in accordance with the Listing Rules and other securities regulatory rules of which the shares of the Company are [REDACTED];
- xi. Decide on the setup of our Company’s internal management organization;
- xii. Appoint or dismiss the general manager of our Company based on the nomination of the chairman of Board of Directors, the secretary of the Board of Directors and other senior management; based on the nomination of the general manager, appoint or dismiss senior management of our Company such as vice manager, chief financial officer and other senior management, and determine their remuneration;
- xiii. Set the basic management systems of our Company;

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- xiv. Make the modification plan to the Articles of Association;
- xv. Manage the disclosure of company information;
- xvi. Propose the appointment or replacement of the accounting firm that performs audits for our Company at the general Shareholders’ meeting;
- xvii. Attend to the work report of our Company’s general manager and review the work of the general manager;
- xviii. Other powers and duties authorized by the laws, administrative regulations, regulations of the authorities, the Listing Rules and other securities regulatory rules of the place where the shares of our Company are [REDACTED] and the Articles of Association.

Meetings of the Board of Directors shall be attended by more than one-half of the Directors (including proxies) before the Board of Directors meeting can be convened.

(5) Independent Non-executive Director

At least one-third of member of the Board of Directors of the Company shall be the independent non-executive Directors and the amount shall not be less than three. At least one independent non-executive Director shall have an applicable professional qualification or are equipped with applicable accounting or relevant financial management expertise.

(6) Secretary of the Board of Directors

Our Company shall have secretary of the Board of Directors, who shall be responsible for preparing for General Meetings and meetings of the Board of Directors, the retention of documents, the management of Shareholder materials, the disclosure of information, etc.

(7) Board of Supervisors

Our Company shall set up a Board of Supervisors.

The Board of Supervisors consists of five Supervisors and includes one chairman. The chairman of the Board of Supervisors shall be elected and dismissed by more than a two-thirds vote of the members of the Board of Supervisors.

The Board of Supervisors shall consist of Shareholder’s representatives and employee’s representatives.

Meetings of the Board of Supervisors shall be attended by more than half of the Supervisors before it may be convened. Resolutions of the Board of Supervisors shall require approval from two-third of all the Supervisors. The Supervisors serve three-year terms.

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The Supervisors may, after the expiration of the term of office, be re-elected and re-appointed.

The Directors and senior management shall not also serve as Supervisors.

The Board of Supervisors is responsible for the general Shareholders' meeting and lawfully exercises the following powers:

- i. Review the company's periodic reports prepared by the Board of Directors and provide written review opinions;
- ii. Examine the financial standing of our Company;
- iii. Supervise the Company's duties performing of Directors and senior management, and put forward suggestions for dismissing any Directors or senior management who are in breach of the laws, administrative regulations, the Articles of Association or resolutions of the general Shareholders' meetings;
- iv. Require the Directors and senior management to take corrective measures when their actions are detrimental to the Company's interests;
- v. Propose to convene an extraordinary general Shareholders' meeting, and where the Board of Directors fails to perform the duties in relation, to convene or preside over the general Shareholders' meeting, to convene and preside over the general Shareholders' meeting;
- vi. Submit proposals at the general Shareholders' meetings;
- vii. Bring actions against the Directors and senior management according to Article 151 of the Company Law;
- viii. Investigate into any abnormalities in operation of our Company; if necessary, to engage accounting firms, law firms and other professional institutions to assist its work, and the expenses shall be borne by our Company;
- ix. Verify the financial information such as the financial reports, business reports and profit distribution plans to be submitted by the Board to the general Shareholders' meetings and, should any queries arise, to authorize, in the name of our Company, a re-examination by the certified public accountants and practicing auditors;
- x. Other powers and duties stipulated in the Articles of Association and authorized by the general shareholder's meetings.

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The Board of Supervisors could investigate into any abnormalities in operation of our Company. If necessary, the Board of Supervisors could engage accounting firms, law firms and other professional institutions to assist its work, and the expenses shall be borne by our Company.

The Supervisors may attend the meetings of the Board of Directors, query or provide suggestions on the resolution matters of the Board meeting.

(8) General manager

Our Company has one general manager, appointed or dismissed by the Board of Directors. The general manager of our Company is responsible to the Board of Directors and exercises the following powers:

- i. Be in charge of the producing and operational management of our Company, organize the enforcement of resolutions of the Board of Directors and report to the Board of Directors on work;
- ii. Organize the implementation of the annual operation plans and investment schemes decided by the Board of Directors;
- iii. Formulate the structure scheme of the internal department of our Company;
- iv. Formulate the fundamental management rules of our Company;
- v. Formulate the specific regulations of our Company;
- vi. Propose the appointment or dismissal of the Company’s vice general manager, chief financial officer to the Board of Directors;
- vii. Appoint or dismiss other management personnel except those who shall be appointed or dismissed by the Board of Directors;
- viii. Other responsibilities authorized by the Articles of Association, the Board of Directors and chairman of the Board of Directors.

(9) Reserves

When the annual after-tax earnings of our Company are distributed, our Company must allocate 10% of the earnings to the statutory reserve of the Company.

When the total amount of the statutory reserve exceeds 50% of our Company’s registered capital, no more allocations need to be drawn.

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If the Company’s statutory reserve is insufficient to offset our losses during the previous year, the earnings generated during the current year must be used to make up the losses before allocating the statutory reserve in accordance with the requirements set forth above.

After allocation to the statutory reserve from the after-tax earnings of our Company, we may also allocate to the reserves at will from after-tax earnings in line with the resolution(s) adopted at the general Shareholders’ meeting.

After our Company has made up for its losses and made allocations to its statutory reserve fund, the remaining profits are distributed in proportion to the number of shares held by the Shareholders, unless otherwise specified by the Articles of Association.

If the general Shareholders’ meeting or Directors violates the above provisions and profits are distributed to the Shareholders before the Company makes up for losses or makes allocations to the statutory reserve fund, the profits distributed in violation of the provisions must be returned by such Shareholders to the Company.

The shares held by our Company itself shall not be subject to profit distribution.

The Company’s reserves must be used only for offsetting losses of the Company, expanding the scale of business and operations or for conversion into capital to increase our capital, but the capital reserve shall not be used to offset losses of the Company.

Where the statutory reserve converses into capital, the remaining statutory reserve shall not be less than 25% of the registered capital of our Company before such conversion.

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FURTHER INFORMATION ABOUT THE COMPANY

Incorporation

The Company was established as a limited liability company under the laws of the PRC on July 8, 2010 and was converted into a joint stock company with limited liability on January 13, 2022. As of the Latest Practicable Date, the registered capital of the Company was RMB182,000,000.

The Company has established a place of business in Hong Kong at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong. The Company was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) and the Companies (Non-Hong Kong Companies) Regulation (Chapter 622J of the Laws of Hong Kong) on December 9, 2022, with Ms. Lai Janette Tin Yun (賴天恩), one of the joint company secretaries of the Company, appointed as the Hong Kong authorised representative of the Company for acceptance of the service of process and any notices required to be served on the Company in Hong Kong.

As the Company was incorporated in the PRC, its operations are subject to the relevant laws and regulations of the PRC. A summary of the relevant aspects of laws and regulations of the PRC and the Articles of Association is set out in Appendix IV and Appendix V to this document, respectively.

Changes in Share Capital of the Company

Save as disclosed in “History, Development and Corporate Structure,” there has been no alteration in the share capital of the Company within two years immediately preceding the date of this document.

Changes in Share Capital of Our Subsidiaries

Details of our subsidiaries is set out in “History, Development and Corporate Structure – Our Subsidiaries” and Note [1] to the Accountants’ Report as set out in Appendix I to this document.

Save as disclosed in “History, Development and Corporate Structure – Our Subsidiaries,” there has been no alteration in the registered capital of our subsidiaries within two years immediately preceding the date of this document.

Resolutions Passed by the Shareholders

At the extraordinary general meeting of the Company held on November 11, 2022, among other things, the following resolutions were passed by the Shareholders:

- (i) the issue by the Company of H Shares of nominal value of RMB1.00 each and such H Shares be [REDACTED] on the Stock Exchange;

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- (ii) the number of H shares to be issued shall be no more than approximately 25% of the total enlarged share capital upon completion of the [REDACTED] (before the exercise of the [REDACTED]), and the grant of the [REDACTED] in respect of no more than 15% of the above number of H Shares to be issued pursuant to this resolution;
- (iii) subject to the CSRC’s approval, upon completion of the [REDACTED], [REDACTED] Shares in aggregate held by CSPC-NBP, Caizhi No. 2, Huiyou Xingyao, Long Star Growth, Hainan Boyou, Guangrui Hongxiang, Zhongheng Tongde, Gongqingcheng Huiyou, Hainan Weifeng, Guangdong Xingyao, Qianshan Xingrong, Sanhua Hongdao, Shaoshan Hongyu and Baiying Huizhi will be converted into H Shares on a one-for-one basis;
- (iv) the grant to the Directors of general mandate to separately or concurrently allot, issue and deal with additional Shares, and the number of such Shares shall not exceed 20% of the Shares in issue, respectively, as of the [REDACTED];
- (v) the authorization of the Board or its authorized individual to handle all matters relating to, among other things, the [REDACTED], the issue and [REDACTED] of H Shares on the Stock Exchange; and
- (vi) subject to the completion of the [REDACTED], the conditional adoption of the revised Articles of Association, which shall become effective on the [REDACTED].

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on June 2, 2023, among other matters, the Articles of Association was further amended, approved and adopted and shall become effective upon the [REDACTED].

FURTHER INFORMATION ABOUT OUR BUSINESS

Summary of Material Contracts

The Group has entered into the following contracts (not being contracts entered into in the ordinary course of business) within the two years immediately preceding the date of this document that are or may be material:

- (i) the capital contribution agreement of the Company in an aggregate amount of RMB20 million, dated June 18, 2021 entered into among Guangdong Xingyao No. 4 Equity Investment Partnership (Limited Partnership) (廣東星耀四號股權投資合夥企業(有限合夥)), Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司), CSPC NBP Pharmaceutical Co., Ltd. (石藥集團恩必普藥業有限公司), Yuan Qian (袁謙), Dr. Zhou Hongfeng (周宏峰), Dr. Zhou Pengfei, Wuhan Caizhi Investment Management Partnership (Limited Partnership) (武漢才智投資管理合夥企業(有限合夥)), Hainan Boyou Enterprise Management Consulting Center (Limited Partnership) (海南博友企業管理諮詢中心(有限合夥)), Ningbo Meishan Bonded Port Area Guangrui Hongxiang Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區廣瑞弘祥股權投資合夥企業(有限合夥)), Long Star Growth Group Limited (長星成長集團有限公司), Nanning Zhongheng Tongde Pharmaceutical Industry Investment Fund Partnership (Limited Partnership) (南寧中

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恒同德醫藥產業投資基金合夥企業(有限合夥)), Dr. Guo Hongwei (郭宏偉), Nanning Huiyou Xingyao Equity Investment Fund Partnership (Limited Partnership) (南寧匯友興曜股權投資基金合夥企業(有限合夥)), Hangzhou Sanhua Hongdao Venture Capital Partnership (Limited Partnership) (杭州三花弘道創業投資合夥企業(有限合夥)), Nanjing BGI Co-win Fund I Venture Capital Enterprise (Limited Partnership) (南京華大共贏一號創業投資企業(有限合夥)), Hainan Weifeng Network Technology Partnership (Limited Partnership) (海南偉豐網絡科技合夥企業(有限合夥)), Shaoshan Hongyu Technology Co., Ltd (韶山鴻宇科技有限公司), Wuhan Baiying Huizhi Venture Capital Fund Partnership (Limited Partnership) (武漢百贏匯智創業投資基金合夥企業(有限合夥)) and Zhuhai Shengyi Investment Partnership (Limited Partnership) (珠海盛溢投資合夥企業(有限合夥)), in relation to the increase of registered capital of the Company;

- (ii) the capital contribution agreement of the Company in an aggregate amount of RMB16 million, dated August 9, 2021 entered into among Suqian Qianshan Xinrong Venture Capital Partnership (Limited Partnership) (宿遷千山信榮創業投資合夥企業(有限合夥)) (formerly known as Heilongjiang Qianshan Xinrong Equity Investment Partnership (Limited Partnership) (黑龍江千山信榮股權投資合夥企業(有限合夥))), Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司), CSPC NBP Pharmaceutical Co., Ltd. (石藥集團恩必普藥業有限公司), Yuan Qian (袁謙), Dr. Zhou Hongfeng (周宏峰), Dr. Zhou Pengfei, Wuhan Caizhi Investment Management Partnership (Limited Partnership) (武漢才智投資管理合夥企業(有限合夥)), Hainan Boyou Enterprise Management Consulting Center (Limited Partnership) (海南博友企業管理諮詢中心(有限合夥)), Ningbo Meishan Bonded Port Area Guangrui Hongxiang Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區廣瑞弘祥股權投資合夥企業(有限合夥)), Long Star Growth Group Limited (長星成長集團有限公司), Nanning Zhongheng Tongde Pharmaceutical Industry Investment Fund Partnership (Limited Partnership) (南寧中恒同德醫藥產業投資基金合夥企業(有限合夥)), Dr. Guo Hongwei (郭宏偉), Nanning Huiyou Xingyao Equity Investment Fund Partnership (Limited Partnership) (南寧匯友興曜股權投資基金合夥企業(有限合夥)), Hangzhou Sanhua Hongdao Venture Capital Partnership (Limited Partnership) (杭州三花弘道創業投資合夥企業(有限合夥)), Nanjing BGI Co-win Fund I Venture Capital Enterprise (Limited Partnership) (南京華大共贏一號創業投資企業(有限合夥)), Hainan Weifeng Network Technology Partnership (Limited Partnership) (海南偉豐網絡科技合夥企業(有限合夥)), Shaoshan Hongyu Technology Co., Ltd (韶山鴻宇科技有限公司), Wuhan Baiying Huizhi Venture Capital Fund Partnership (Limited Partnership) (武漢百贏匯智創業投資基金合夥企業(有限合夥)) and Zhuhai Shengyi Investment Partnership (Limited Partnership) (珠海盛溢投資合夥企業(有限合夥)), in relation to the increase of registered capital of the Company;
- (iii) the capital contribution agreement of the Company in an aggregate amount of RMB37.5 million, dated August 17, 2021 entered into among Gongqingcheng Huiyou Xingyao Phase II Equity Investment Partnership (Limited Partnership) (共青城匯友興曜二期股權投資合夥企業(有限合夥)), Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司), CSPC NBP Pharmaceutical Co., Ltd. (石藥集

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團恩必普藥業有限公司), Yuan Qian (袁謙), Dr. Zhou Hongfeng (周宏峰), Dr. Zhou Pengfei, Wuhan Caizhi Investment Management Partnership (Limited Partnership) (武漢才智投資管理合夥企業(有限合夥)), Hainan Boyou Enterprise Management Consulting Center (Limited Partnership) (海南博友企業管理諮詢中心(有限合夥)), Ningbo Meishan Bonded Port Area Guangrui Hongxiang Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區廣瑞弘祥股權投資合夥企業(有限合夥)), Long Star Growth Group Limited (長星成長集團有限公司), Nanning Zhongheng Tongde Pharmaceutical Industry Investment Fund Partnership (Limited Partnership) (南寧中恒同德醫藥產業投資基金合夥企業(有限合夥)), Dr. Guo Hongwei (郭宏偉), Nanning Huiyou Xingyao Equity Investment Fund Partnership (Limited Partnership) (南寧匯友興曜股權投資基金合夥企業(有限合夥)), Hangzhou Sanhua Hongdao Venture Capital Partnership (Limited Partnership) (杭州三花弘道創業投資合夥企業(有限合夥)), Nanjing BGI Co-win Fund I Venture Capital Enterprise (Limited Partnership) (南京華大共贏一號創業投資企業(有限合夥)), Hainan Weifeng Network Technology Partnership (Limited Partnership) (海南偉豐網絡科技合夥企業(有限合夥)), Shaoshan Hongyu Technology Co., Ltd (韶山鴻宇科技有限公司), Wuhan Baiying Huizhi Venture Capital Fund Partnership (Limited Partnership) (武漢百贏匯智創業投資基金合夥企業(有限合夥)) and Zhuhai Shengyi Investment Partnership (Limited Partnership) (珠海盛溢投資合夥企業(有限合夥)), in relation to the increase of registered capital of the Company;

- (iv) the capital contribution agreement of the Company in an aggregate amount of RMB200 million, dated July 15, 2022 entered into among Wuhan Optics Valley New Technology Industry Investment Co., Ltd (武漢光穀新技術產業投資有限公司), Wuhan Optics Valley Health Industry Investment Ltd. (武漢光穀健康產業投資有限公司), Wuhan Optics Valley Growth Venture Capital Fund Co., Ltd (武漢光穀成長創業投資基金有限公司), Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司), CSPC NBP Pharmaceutical Co., Ltd. (石藥集團恩必普藥業有限公司), Yuan Qian (袁謙), Dr. Zhou Hongfeng (周宏峰), Dr. Zhou Pengfei, Wuhan Caizhi Investment Management Partnership (Limited Partnership) (武漢才智投資管理合夥企業(有限合夥)), Hainan Boyou Enterprise Management Consulting Center (Limited Partnership) (海南博友企業管理諮詢中心(有限合夥)), Ningbo Meishan Bonded Port Area Guangrui Hongxiang Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區廣瑞弘祥股權投資合夥企業(有限合夥)), Long Star Growth Group Limited (長星成長集團有限公司), Nanning Zhongheng Tongde Pharmaceutical Industry Investment Fund Partnership (Limited Partnership) (南寧中恒同德醫藥產業投資基金合夥企業(有限合夥)), Dr. Guo Hongwei (郭宏偉), Nanning Huiyou Xingyao Equity Investment Fund Partnership (Limited Partnership) (南寧匯友興曜股權投資基金合夥企業(有限合夥)), Hangzhou Sanhua Hongdao Venture Capital Partnership (Limited Partnership) (杭州三花弘道創業投資合夥企業(有限合夥)), Nanjing BGI Co-win Fund I Venture Capital Enterprise (Limited Partnership) (南京華大共贏一號創業投資企業(有限合夥)), Hainan Weifeng Network Technology Partnership (Limited Partnership) (海南偉豐網絡科技合夥企業(有限合夥)), Shaoshan Hongyu Technology Co., Ltd (韶山鴻宇科技有限公司), Wuhan Baiying Huizhi Venture Capital Fund Partnership (Limited Partnership) (武

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漢百贏匯智創業投資基金合夥企業(有限合夥)), Zhuhai Shengyi Investment Partnership (Limited Partnership) (珠海盛溢投資合夥企業(有限合夥)), Suqian Qianshan Xinrong Venture Capital Partnership (Limited Partnership) (宿遷千山信榮創業投資合夥企業(有限合夥)) (formerly known as Heilongjiang Qianshan Xinrong Equity Investment Partnership (Limited Partnership) (黑龍江千山信榮股權投資合夥企業(有限合夥))), Guangdong Xingyao No.4 Equity Investment Partnership (Limited Partnership) (廣東星耀四號股權投資合夥企業(有限合夥)), Gongqingcheng Huiyou Xingyao Phase II Equity Investment Partnership (Limited Partnership) (共青城匯友興曜二期股權投資合夥企業(有限合夥)) and Nanjing Caizhi No. 2 Enterprise Management Partnership (Limited Partnership) (南京才智二號企業管理合夥企業(有限合夥)), in relation to the increase of registered capital of the Company;

(v) the [REDACTED]; and

(vi) [●].

Intellectual Property Rights

Trademarks

As of the Latest Practicable Date, the Group had registered or applied for registration the following trademarks which are material to its business:

No.	Trademark	Class	Registered Owner/ Applicant	Place of Registration	Registration/ Application Number	Date of Registration/ Application	Expiry Date
1	友芝友生物	5, 35, 42	The Company	HK	305896847	March 4, 2022	March 3, 2032
2	YZY BIOPHARMA	5, 42	The Company	HK	305896829	March 4, 2022	March 3, 2032
	zyz biopharma						
	YZY biopharma						
	YZY Biopharma						

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No.	Trademark	Class	Registered Owner/ Applicant	Place of Registration	Registration/ Application Number	Date of Registration/ Application	Expiry Date
3	 友芝友生物製藥  友芝友生物製藥  友芝友生物製藥  友芝友生物製藥	5, 42	The Company	HK	305896838	March 4, 2022	March 3, 2032
4	YBODY	42	The Company	PRC	9420741	June 14, 2022	June 13, 2032
5	YBODY	10	The Company	PRC	9420491	May 21, 2022	May 20, 2032
6	YBODY	5	The Company	PRC	9420430	May 21, 2022	May 20, 2032
7		42	The Company	PRC	9229704	May 14, 2022	May 13, 2032
8		10	The Company	PRC	9229665	March 28, 2022	March 27, 2032
9	YouVax	10	The Company	PRC	53226327	October 28, 2021	October 27, 2031
10	YourVax	35	The Company	PRC	53213579	October 28, 2021	October 27, 2031
11	UVAX	5	The Company	PRC	53199800	September 7, 2021	September 6, 2031
12	YourVax	44	The Company	PRC	53217859	August 28, 2021	August 27, 2031
13	UVAX	10	The Company	PRC	53212454	August 28, 2021	August 27, 2031
14	YourVax	5	The Company	PRC	53202411	August 28, 2021	August 27, 2031
15	YourVax	10	The Company	PRC	53216899	August 21, 2021	August 20, 2031
16	YourVax	42	The Company	PRC	53203890	August 21, 2021	August 20, 2031
17	FF-BODY	42	The Company	PRC	32102319	May 14, 2019	May 13, 2029
18	FF-BODY	10	The Company	PRC	32085254	May 7, 2019	May 6, 2029

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No.	Trademark	Class	Registered Owner/ Applicant	Place of Registration	Registration/ Application Number	Date of Registration/ Application	Expiry Date
19	FF-BODY	5	The Company	PRC	32093023	April 21, 2019	April 20, 2029
20	友脉	5	The Company	PRC	32089019	April 14, 2019	April 13, 2029
21	YOUMAB	5	The Company	PRC	32086698	April 7, 2019	April 6, 2029
22	友脉	10	The Company	PRC	32085852	March 28, 2019	March 27, 2029
23		42	The Company	PRC	14264056	June 14, 2015	June 13, 2025
24		5	The Company	PRC	14263905	June 14, 2015	June 13, 2025
25		10	The Company	PRC	14264008	May 7, 2015	May 6, 2025
26	YZYBIO	5	The Company	PRC	10812647	July 21, 2013	July 20, 2023
27	YouVax	5	The Company	PRC	53226296	December 28, 2021	December 27, 2031
28	YZY BIOPHARMA	42	The Company	PRC	62890235	February 28, 2022	N/A
29	YZY BIOPHARMA	10	The Company	PRC	62891816	February 28, 2022	N/A
30	YZY BIOPHARMA	35	The Company	PRC	62889058	February 28, 2022	N/A
31	YZY BIOPHARMA	5	The Company	PRC	62902281	February 28, 2022	N/A

Domain Names

As of the Latest Practicable Date, the Group had registered the following domain names which are material to its business:

No.	Domain Name	Registered Owner	Expiry Date
1	zybio.cn	The Company	May 22, 2027
2	zybio.com	The Company	October 28, 2027

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Patents

For a discussion of the details of the material granted patents and filed patent applications by the Company in connection with our clinical and pre-clinical products, please refer to the paragraphs headed “Business – Intellectual Property” in this document.

Save as disclosed above, as of the Latest Practicable Date, there were no other intellectual property rights which are material to the business of the Group.

DISCLOSURE OF INTERESTS

Disclosure of Interests of Directors, Supervisors and Chief Executive of the Company

Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised) and the conversion of the [REDACTED] Shares into H Shares, the interests and/or short positions (as applicable) of the Directors, Supervisors and the chief executive of the Company in the Shares, underlying Shares and debentures of the Company and any interests and/or short positions (as applicable) in shares, underlying shares or debentures of any of the Company’s associated corporations (within the meaning of Part XV of the SFO) which (i) will have to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and/or short positions (as applicable) which they are taken or deemed to have under such provisions of the SFO), (ii) will be required, pursuant to Section 352 of the SFO, to be entered in the register referred to therein or (iii) will be required, pursuant to the Model Code for Securities Transactions by Directors of [REDACTED] Issuers as set out in Appendix 10 to the Listing Rules, to be notified to the Company and the Stock Exchange, in each case once the Shares are [REDACTED] on the Stock Exchange, will be as follows:

Name of Director, Supervisor or Chief Executive	Nature of Interest	Description of the Shares ⁽⁴⁾	Number of Shares Held or Interested	Approximate percentage of interest in the Company ⁽¹⁾	Approximate percentage of interest in the [REDACTED] Shares/ H Shares (as appropriate) Shares ⁽¹⁾⁽⁴⁾
Yuan Qian ⁽²⁾	Beneficial owner; interest held jointly with other persons	[REDACTED] Shares	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Zhou Pengfei ⁽²⁾	Beneficial owner; interest held jointly with other persons	[REDACTED] Shares	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Zhou Hongfeng ⁽²⁾	Beneficial owner; interest held jointly with other persons	[REDACTED] Shares	[REDACTED]	[REDACTED]	[REDACTED]

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Name of Director, Supervisor or Chief Executive	Nature of Interest	Description of the Shares ⁽⁴⁾	Number of Shares Held or Interested	Approximate percentage of interest in the Company ⁽¹⁾	Approximate percentage of interest in the [REDACTED]
					Shares/ H Shares (as appropriate) Shares ⁽¹⁾⁽⁴⁾
Dr. Guo Hongwei ⁽³⁾	Beneficial owner	[REDACTED] Shares	[REDACTED]	[REDACTED]	[REDACTED]
	Interest in controlled corporations	[REDACTED] Shares	[REDACTED]	[REDACTED]	[REDACTED] ([REDACTED] Shares)
		H Shares	[REDACTED]	[REDACTED]	[REDACTED] (H Shares)

- (1) The calculation is based on the total number of [REDACTED] Shares and [REDACTED] H Shares in issue immediately following the completion of the [REDACTED] (without taking into account the H Shares which may be [REDACTED] upon the exercise of the [REDACTED]) and the conversion of the [REDACTED] Shares into H Shares.
- (2) Pursuant to the Concert Party Agreement and supplemental concert party agreements dated October 26, 2020 and June 2, 2023 entered into among the AIC Parties, the AIC Parties agreed (i) to act in concert by way of reaching consensus on proposals related to the Group’s daily management and operation presented to all general meetings and Board meetings of the Company; and (ii) that when no consensus can be reached, the AIC Parties shall vote in concurrence with Yuan Qian on the proposals, or, in the event of Yuan Qian’s absence from voting, the AIC Parties shall vote in concurrence with the AIC Party with the highest shareholding percentage among the AIC Parties who votes at the meetings. As a result, each of the AIC Parties was deemed to be interested in (i) the aggregate of [REDACTED] Domestic Shares held by Yuan Qian, Dr. Zhou Hongfeng and Wuhan Caizhi, and (ii) the [REDACTED] Foreign Shares held by Dr. Zhou Pengfei.
- (3) As of the Latest Practicable Date, (i) Nanning Yaoyou was the general partner of Huiyou Xingyao; and (ii) Dr. Guo Hongwei was the limited partner of Nanning Yaoyou with the limited partnership interests of 33.00%. As a result, Dr. Guo Hongwei was deemed to be interested in the [REDACTED] H Shares and [REDACTED] Domestic Shares held by Huiyou Xingyao under the SFO.
- (4) For the avoidance of doubt, both [REDACTED] Shares and H Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares.

Save as disclosed above, none of the Directors, Supervisors or the chief executive of the Company will, immediately following the completion of the [REDACTED] and the conversion of the [REDACTED] Shares into H Shares, have an interest and/or short position (as applicable) in the Shares, underlying Shares or debentures of the Company or any interests and/or short positions (as applicable) in the shares, underlying shares or debentures of the Company’s associated corporations (within the meaning of Part XV of the SFO) which (i) will have to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they are taken or deemed to have under such provisions of the SFO), (ii) will be required, pursuant to Section 352 of the SFO, to be entered in the register referred to therein or (iii) will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules, to be notified to the Company and the Stock Exchange, in each case once the Shares are [REDACTED] on the Stock Exchange.

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Disclosure of Interests of Substantial Shareholders

Save as disclosed in “Substantial Shareholders” in this document, our Directors are not aware of any other person who will, immediately following the completion of the [REDACTED] and the conversion of the [REDACTED] Shares into H Shares, have an interest and/or short position in the Shares or underlying Shares which are required to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or, directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying the rights to vote in all circumstances at the general meetings of the Company or any other members of the Group.

FURTHER INFORMATION ABOUT DIRECTORS AND SUPERVISORS

Particulars of the Service Contracts

Pursuant to Rules 19A.54 and 19A.55 of the Hong Kong Listing Rules, we have entered into a contract with each of the Directors and Supervisors in respect of, among other things, (i) compliance with relevant laws and regulations, (ii) observance of the Articles of Association, and (iii) provisions on arbitration.

Save as disclosed above, none of the Directors or Supervisors has entered or is proposed to enter into any service contracts as a director or supervisor with any member of the Group (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation)).

Remuneration of Directors and Supervisors

For details of the remuneration of Directors and Supervisors, please refer to the paragraphs headed “Directors, Supervisors and Senior Management – Directors’, Supervisors’ and Chief Executive Officer’s Remuneration and Remuneration of the Five Highest-paid Individuals” and Note 12 to the Accountants’ Report as set out in Appendix I to this document.

Agency Fees or Commissions Received

The [REDACTED] will receive an [REDACTED] in connection with the [REDACTED], as detailed in “[REDACTED]”. Save in connection with the [REDACTED], no [REDACTED], discounts, [REDACTED] or other special terms have been granted by the Group to any person (including the Directors, promoters and experts referred to in “– Other Information – Qualifications and Consents of Experts” below) in connection with the issue or sale of any capital or security of the Company or any member of the Group within the two years immediately preceding the date of this document.

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Within the two years immediately preceding the date of this document, no [REDACTED] has been paid or is payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription for any share in or debentures of the Company.

Personal Guarantees

The Directors have not provided personal guarantees in favor of lenders in connection with banking facilities granted to the Group.

Disclaimers

- (i) Save as disclosed in “History, Development and Corporate Structure,” none of the Directors, Supervisors nor any of the experts referred to in “– Other Information – Qualifications and Consents of Experts” below has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by, or leased to, any member of the Group, or are proposed to be acquired or disposed of by, or leased to, any member of the Group;
- (ii) Save in connection with the [REDACTED], none of the Directors, Supervisors nor any of the experts referred to in “– Other Information – Qualifications and Consents of Experts” below, is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of the Group;
- (iii) None of the Directors is interested in any business apart from the Group’s business which competes or is likely to compete, directly or indirectly, with the business of the Group;
- (iv) No cash, securities or other benefit has been paid, allotted or given within the two years preceding the date of this document to any promoter of the Company nor is any such cash, securities or benefit intended to be paid, allotted or given on the basis of the [REDACTED] or related transactions as mentioned;
- (v) So far as is known to the Directors, none of the Directors or their associates or any Shareholders who are expected to be interested in 5% or more of the issued share capital of the Company has any interest in the five largest customers or the five largest suppliers of the Group; and
- (vi) Save as disclosed in this document, none of the Directors or Supervisors is aware of any person (not being a Director or chief executive of the Company) who will, immediately following completion of the [REDACTED] (without taking into account any Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]) and the conversion of the [REDACTED] Shares into H Shares, have an interest or short position in the Shares or underlying Shares which would fall to be disclosed to the Company under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of the Group.

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EMPLOYEE INCENTIVE SCHEMES

The following is a summary of the principal terms of the two employee incentive schemes adopted by our Company, namely the Wuhan Caizhi Employee Incentive Scheme of Wuhan YZY Biopharma Co., Ltd. (the “**Wuhan Caizhi Employee Incentive Scheme**”) and the Caizhi No.2 Employee Incentive Scheme of Wuhan YZY Biopharma Co., Ltd. (the “**Caizhi No.2 Employee Incentive Scheme**”) (collectively, the “**Employee Incentive Schemes**”). The Employee Incentive Schemes do not involve any grant of share options or awards after the [REDACTED] and therefore are not subject to the provisions of Chapter 17 of the Listing Rules.

The Employee Incentive Schemes aim to further improve the corporate governance structure of the Company, fully stimulate the enthusiasm of the management members and personnel of the Company, enhance the Company’s overall competitiveness, and ensure the achievement of the business objectives of the future development strategy of the Company.

The shareholders’ meeting of the Company is responsible for considering and approving the Employee Incentive Schemes, and has authorized the general manager of the Company to formulate and revise the Employee Incentive Schemes. The Supervisory Committee, as the supervisory body of the Employee Incentive Schemes, is responsible for monitoring whether the implementation of the Employee Incentive Schemes complies with the relevant laws, administrative regulations, departmental rules and the Articles of Association.

An award under the Employee Incentive Schemes (the “**Award(s)**”) gives a participant in the Employee Incentive Schemes a right when granted the Award to obtain partnership interest in the Employee Incentive Platforms (as defined below) and Caizhi No.2 as a limited partner.

Wuhan Caizhi Employee Incentive Scheme

Wuhan Caizhi Employee Incentive Scheme was adopted by our Company on July 1, 2017 and further amended on January 18, 2019, August 20, 2021 and December 30, 2021, respectively.

Principal Terms

Implementation structure and platforms

Wuhan Caizhi, Huiyou Jucai and Huiyou Juzhi were established to serve as the employee incentive platforms (the “**Employee Incentive Platforms**”). Wuhan Caizhi is a limited partnership established in the PRC on September 21, 2015 and managed by its executive partner, Yuan Qian. In order to include more participants in the Wuhan Caizhi Employee Incentive Scheme, Huiyou Jucai and Huiyou Juzhi were later established in the PRC on August 26, 2021 and August 27, 2021, respectively, which are both managed by Dr. Zhou Pengfei as the general partner. Some of the participants indirectly held partnership interest in Wuhan

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Caizhi through holding partnership interest in Huiyou Jucai and/or Huiyou Juzhi. As of the Latest Practicable Date, Huiyou Jucai and Huiyou Juzhi held approximately 50.76% and 29.33% partnership interest in Wuhan Caizhi, respectively.

For more details, please refer to the paragraphs headed “History, Development and Corporate Structure – Employee Incentive Platforms – Wuhan Caizhi” in this document.

Eligible participants and grants of the Awards

Under the Wuhan Caizhi Employee Incentive Scheme, eligible participants are the senior management members or employees determined by Dr. Zhou Pengfei as authorized by Yuan Qian and Dr. Zhou Hongfeng, subject to Yuan Qian and Dr. Zhou Hongfeng’s approval. The following individuals may not be selected as participants under the Wuhan Caizhi Employee Incentive Scheme:

- Individuals who were publicly denounced or declared as an unsuitable candidate by a stock exchange within the last three years before the approval of the Wuhan Caizhi Employee Incentive Scheme;
- Individuals who were subject to administrative penalty by the CSRC for major violation of laws and regulations within the last three years before the approval of the Wuhan Caizhi Employee Incentive Scheme;
- Individuals who are subject to criminal liability due to reasons including severe negligence and malfeasance;
- Individuals who have seriously violated the Company’s management system, or caused significant economic losses to the Company, or caused material negative impact on the Company, and been subject to the Company’s disciplinary action;
- Individuals who forcefully and voluntarily resign without approval from the Company;
- Individuals whose labor contract with the Company is terminated by the Company due to personal fault; or
- Individuals who fail to meet the requirements under the Annual Targets Responsibility Letter by the Company and fail in the individual performance evaluation for the preceeding year.

The participants of the Wuhan Caizhi Employee Incentive Scheme will be granted the Awards under the Wuhan Caizhi Employee Incentive Scheme, where they are given a right to obtain partnership interest in the Employee Incentive Platforms as limited partners. The participants should be full-time employees of the Company at the time of becoming limited partners of the Employee Incentive Platforms, and should enter into a participation agreement

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with other partners according to the partnership interest which is determined by Dr. Zhou Pengfei as authorized by Yuan Qian and Dr. Zhou Hongfeng and subject to Yuan Qian and Dr. Zhou Hongfeng’s approval, and enjoy the rights and take responsibility under the partnership agreement of Employee Incentive Platforms.

Lock-up period

The lock-up period of the Wuhan Caizhi Employee Incentive Scheme shall be from the date on which the participants become limited partners of the Employee Incentive Platforms to one year after the Company’s shares being [REDACTED] on a foreign stock exchange (the “**Lock-up Period of Wuhan Caizhi**”). Subject to the relevant PRC laws, rules and regulations, during the Lock-up Period of Wuhan Caizhi, the Employee Incentive Platforms shall not accept the participants’ requests for sale of the underlying Shares of the Awards granted to them and the Shares held by the Employee Incentive Platforms should not be transferred.

Distribution and exit mechanisms for limited partners

After the expiration of the Lock-up Period of Wuhan Caizhi, the participants, being limited partners, may make requests for sale of the underlying Shares of the Awards granted to them under the Wuhan Caizhi Employee Incentive Scheme so that they can cash out their economic interests in the Shares. The sale requests should be collected from time to time and submitted to the executive partner of Wuhan Caizhi for approval. Upon the executive partner’s approval, Wuhan Caizhi should sell the Shares under the requests accordingly in the secondary market. The Employee Incentive Platforms and their respective executive partners should carry out the capital reduction procedures or partnership exit procedures because of such sale of Shares.

The participants should be mandatorily removed from the limited partnership where: (1) the participants violate the national criminal laws and are penalized; (2) the participants violate the relevant national laws, administrative regulations or Articles of Association and cause economic loss to the Company; (3) the participants’ labor contracts are terminated due to severe violation of rules and regulations of the Company; (4) the participants forcefully and voluntarily resign without approval from the Company; (5) the participants are in severe dereliction of duty or malfeasance; (6) the Company has evidence showing that during his or her term of office, the participant has conducted bribery, solicited bribes, embezzlement, theft, leakage of business and technical secrets, peer competition or other conducts in violation of laws and regulations which damaged the interest and reputation of the Company; or (7) the participants has conducted other acts deemed by the Shareholders’ meeting of the Company to have damaged the interest and reputation of the Company.

If the participant is mandatorily removed due to reasons above, such participant’s partnership interest in the Employee Incentive Platforms should be repurchased by the founders of the Company, namely Yuan Qian, Dr. Zhou Hongfeng and Dr. Zhou Pengfei, and may be re-granted to other participants proposed by Dr. Zhou Pengfei as authorized by Yuan Qian and

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Dr. Zhou Hongfeng according to the operation conditions of the Company, subject to Yuan Qian and Dr. Zhou Hongfeng’s consideration and approval. In the case where the interest of the Company has been damaged by the participate, the Company reserves its right of recourse.

Current Partners and Details of the Granted Awards

As of the Latest Practicable Date, Wuhan Caizhi held 16,792,707 Shares, representing approximately 9.23% of the total issued Shares of our Company. The following table sets out the partnership interest in each of the Employee Incentive Platforms and the number of underlying Shares of the Awards granted to our Directors, Supervisors, senior management of the Company (other than our Directors and Supervisors) and other key employees, respectively.

Employee Incentive Platform	Name or identity of the partner	Number of relevant other key employees relative to the specified interest range	Approximate partnership interest in the Employee Incentive Platform (%)	Approximate number of underlying Shares of the Awards granted under the Wuhan Caizhi Employee Incentive Scheme as of the Latest Practicable Date
Wuhan Caizhi	Directors:		8.82	1,481,574
	Dr. Zhou Pengfei		8.28	1,389,978 ⁽²⁾
	Yuan Qian		0.36	61,064 ⁽²⁾
	Dr. Zhou Hongfeng		0.18	30,532 ⁽²⁾
	Supervisor:		4.08	684,464
	Zhang Jing		0.53	88,518
	Dr. Yi Jizu		3.55	595,946
	Other key employees (totaling 20 employees) ⁽¹⁾		7.01	1,177,347
		15	0.02-0.19	258,690
		5	0.28-3.95	918,657
	Huiyou Jucai		50.76	8,523,461
	Huiyou Juzhi		29.33	4,925,861
Total			100	16,792,707⁽²⁾

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Employee Incentive Platform	Name or identity of the partner	Number of relevant other key employees relative to the specified interest range	Approximate partnership interest in the Employee Incentive Platform (%)	Approximate number of underlying Shares of the Awards granted under the Wuhan Caizhi Employee Incentive Scheme as of the Latest Practicable Date
Huiyou				
Jucai	Director:		49.95	4,257,842
	Dr. Zhou Pengfei		49.95	4,257,842
	Supervisor:		23.61	2,012,547
	Zhang Jing		10.90	929,222
	Dr. Yi Jizu		12.71	1,083,325
	Other key employees (totaling 10 employees) ⁽¹⁾ :		26.43	2,253,072
		5	0.57-2.24	728,316
		5	2.26-4.57	1,524,756
Total			100	8,523,461
Huiyou				
Juzhi	Director:		10.33	508,870
	Dr. Zhou Pengfei		10.33	508,870
	Senior management of the Company:		14.46	712,418
	Dr. Huang Shaoyi		10.33	508,869
	Dr. Yang Bin		4.13	203,548
	Other key employees (totaling 36 employees) ⁽¹⁾ :		75.21	3,704,573
		4	0.41-0.62	91,596
		13	1.03-1.45	681,886
		13	1.65-3.10	1,608,029
		6	4.13-6.20	1,323,062
Total			100	4,925,861

(1) For more details on the identities of other key employees as limited partners of each Employee Incentive Platforms under the Wuhan Caizhi Employee Incentive Scheme, please refer to the paragraphs headed “History, Development and Corporate Structure – Employee Incentive Platforms – Wuhan Caizhi” in this document.

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- (2) Pursuant to the Wuhan Caizhi Employee Incentive Scheme, the 0.36% and 0.18% partnership interest in Wuhan Caizhi held by Yuan Qian and Dr. Zhou Hongfeng, respectively, do not constitute the Awards and they cannot make requests for sale of Shares according to the distribution and exit mechanism of the Wuhan Caizhi Employee Incentive Scheme, as they serve as the general partners of Wuhan Caizhi. The 0.06% among the 8.28% partnership interest in Wuhan Caizhi held by Dr. Zhou Pengfei, the general partner of Huiyou Jucai and Huiyou Juzhi, does not constitute the Awards, and as for this part of partnership interest in Wuhan Caizhi, Dr. Zhou Pengfei cannot make requests for sale of the Shares according to the distribution and exit mechanism of the Wuhan Caizhi Employee Incentive Scheme.

Caizhi No.2 Employee Incentive Scheme

Caizhi No.2 Employee Incentive Scheme was adopted by our Company on August 20, 2021 and further amended on December 30, 2021.

Principal Terms

Implementation and platform

In order to implement the Caizhi No.2 Employee Incentive Scheme, Caizhi No.2 was established as the employee incentive platform for the Caizhi No.2 Employee Incentive Scheme. Caizhi No.2 is a limited partnership established in the PRC on August 27, 2021 managed by its general partner, Wuhan Huiyou Juyou Enterprise Management Co., Ltd. (武漢匯友聚友企業管理有限公司), which was in turn owned as to 90% by Dr. Zhou Pengfei and as to 10% by Zhang Jing, our Supervisor, as of the Latest Practicable Date. Pursuant to the partnership agreement of Caizhi No.2, its general partner will exercise its voting power in the Company following the instruction of the management committee of Caizhi No.2. The 11 members of the management committee of Caizhi No.2 consist of six members nominated by CSPC-NBP, Guangrui Hongxiang, Hainan Boyou, Long Star Growth, Yuan Qian and Dr. Zhou Hongfeng (being the shareholders who transferred the equity interest they held in the Company to Caizhi No.2 for its establishment), respectively, and five members nominated by the management team of the Company. All decisions made by the management committee of Caizhi No.2 should be approved by the majority of all members.

Different classes of limited partners

The limited partners of Caizhi No.2 comprise class A limited partners (including CSPC-NBP, Guangrui Hongxiang, Hainan Boyou, Long Star Growth, Yuan Qian and Dr. Zhou Hongfeng, collectively, the “**Class A Limited Partners**”) and class B limited partners (the “**Class B Limited Partners**”).

The Class A Limited Partners transferred 10% of the equity interest they held in the Company, being the registered capital of the Company in a total amount of RMB11,417,860, to Caizhi No.2 as their respective capital contribution in September 2021. For more details on this equity transfer, please refer to the paragraphs headed “History, Development and Corporate Structure – Establishment and Corporate Development – Equity Transfer in September 2021” in this document.

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The participants of the Caizhi No.2 Employee Incentive Scheme are granted the Awards to obtain partnership interest in Caizhi No.2 as Class B Limited Partners Pursuant to the terms of the Caizhi No.2 Employee Incentive Scheme, the price for acquiring the partnership interest in Caizhi No.2 corresponding to the Awards will be paid using the gains generated from sale of Shares held by Caizhi No.2 under the gain distribution mechanism.

Eligible participants and grants of the Awards

Under the Caizhi No.2 Employee Incentive Scheme, eligible participants are the senior management members or employees determined by Dr. Zhou Pengfei as authorized by Class A Limited Partners, subject to Class A Limited Partners’ approval. The participants should be full-time employees of the Company at the time of becoming Class B Limited Partners of Caizhi No.2, and should enter into a participation agreement with other partners according to the partnership interest which is determined by Dr. Zhou Pengfei as authorized by Class A Limited Partners and subject to Class A Limited Partners’ approval, and enjoy the rights and take responsibility as Class B Limited Partners under the partnership agreement of Caizhi No.2.

The following individuals may not be selected as participants under the Caizhi No.2 Employee Incentive Scheme:

- Individuals who were publicly denounced or declared as an unsuitable candidate by a stock exchange within the last three years before the approval of the Employee Incentive Scheme;
- Individuals who were subject to administrative penalty by the CSRC for major violation of laws and regulations within the last three years before the approval of the Caizhi No.2 Employee Incentive Scheme;
- Individuals who are subject to criminal liability due to reasons including severe negligence and malfeasance;
- Individuals who have seriously violated the Company’s management system, or caused significant economic losses to the Company, or caused material negative impact on the Company, and been subject to the Company’s disciplinary action;
- Individuals who forcefully and voluntarily resign without approval from the Company;
- Individuals whose labor contract with the Company is terminated by the Company due to personal fault; or
- Individuals who fail to meet the requirements under the Annual Targets Responsibility Letter by the Company and fail in the individual performance evaluation for the preceding year.

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Lock-up period

The lock-up period of the Caizhi No.2 Employee Incentive Scheme shall be from the date on which the participants become Class B Limited Partners of Caizhi No.2 to one year after the Company’s shares being [REDACTED] on a foreign stock exchange (the “**Lock-up Period of Caizhi No.2**”). Subject to relevant PRC laws, rules and regulations, during the Lock-up Period of Caizhi No.2, the Shares held by Caizhi No.2 should not be transferred.

Distribution and exit mechanisms for limited partners

After the expiration of the Lock-up Period of Caizhi No.2, as instructed by the management committee of Caizhi No.2 from time to time, Caizhi No.2 will annually sell certain number of Shares it holds in the secondary market. Caizhi No.2 should then distribute the capital gains between Class A Limited Partners and Class B Limited Partners pursuant to the terms and conditions under the Caizhi No.2 Employee Incentive Scheme. Class A Limited Partners and Class B Limited Partners will exit from Caizhi No.2 once all their interests under the Caizhi No.2 Employee Incentive Scheme have been realized.

The participants should be mandatorily removed from the limited partnership where: (1) the participants violate the national criminal laws and are penalized; (2) the participants violate the relevant national laws, administrative regulations or Articles of Association and cause economic loss to the Company; (3) the participants’ labor contracts are terminated due to severe violation of rules and regulations of the Company; (4) the participants forcefully and voluntarily resign without approval from the Company; (5) the participants are in severe dereliction of duty or malfeasance; (6) the Company has evidence showing that during his or her term of office, the participant has conducted bribery, solicited bribes, embezzlement, theft, leakage of business and technical secrets, peer competition or other conducts in violation of laws and regulations which damaged the interest and reputation of the Company; or (7) the participants has conducted other acts deemed by the Shareholders’ meeting of the Company to have damaged the interest and reputation of the Company.

If the participant is mandatorily removed due to reasons above, such participant’s partnership interest in Caizhi No.2 should be repurchased by the founders of the Company, namely Yuan Qian, Dr. Zhou Hongfeng and Dr. Zhou Pengfei and may be re-granted to other participants proposed by Dr. Zhou Pengfei as authorized by Class A Limited Partners according to the operation conditions of the Company, subject to Class A Limited Partners’ consideration and approval. In the case where the interest of the Company has been damaged by the participate, the Company reserves its right of recourse.

Current Class B Limited Partners and Details of the Granted Awards

As of the Latest Practicable Date, the Class A Limited Partners, the Class B Limited Partners and the general partner of Caizhi No.2 held 49.98%, 49.98% and 0.04% partnership interest in Caizhi No.2, respectively. As of the Latest Practicable Date, Caizhi No.2 held 11,620,411 Shares, representing approximately 6.38% of the total issued Shares of our

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Company. For details on the partnership interest in Caizhi No.2 respectively held by the Class A Limited Partners and the general partner of Caizhi No.2, please refer to the paragraphs headed “History, Development and Corporate Structure – Employee Incentive Platforms – Caizhi No.2” in this document. The following table sets out the partnership interest in Caizhi No.2 and the number of underlying Shares of the Awards granted to the Class B Limited Partners, including directors, supervisors, senior management of our Group and other key employees who are independent third parties of our Company, respectively.

Name or identity of the Class B Limited Partner	Number of relevant other key employees relative to the specified interest range	Approximate partnership interest in Caizhi No.2 (%)	Approximate number of underlying Shares of the Awards granted under the Caizhi No.2 Employee Incentive Scheme as of the Latest Practicable Date
Director:		23.72	5,513,972
Dr. Zhou Pengfei		23.72	5,513,972
Supervisor:		8.97	2,086,367
Zhang Jing		3.94	915,966
Dr. Yi Jizu		5.03	1,170,401
Other senior management of the Company:		3.06	712,418
Dr. Yang Bin		2.62	610,644
Dr. Huang Shaoyi		0.44	101,774
Other key employees (totaling 10 employees) ⁽¹⁾		14.23	3,307,654
	5	0.44	508,870
	3	0.65-2.19	966,853
	2	3.5-4.38	1,831,931
Total		49.98	11,620,411

(1) For more details on the identities of other key employees as limited partners of Caizhi No.2, please refer to the paragraphs headed “History, Development and Corporate Structure – Employee Incentive Platforms – Caizhi No.2” in this document.

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OTHER INFORMATION

Estate Duty

The Directors have been advised that no material liability for estate duty is likely to fall on the Group under the laws of the PRC.

Litigation

As of the Latest Practicable Date, the Company was not engaged in any outstanding litigation or arbitration which may have material adverse effect on the [REDACTED] and, so far as the Directors are aware, no material litigation or claim was pending or threatened by or against the Company.

Sole Sponsor and Sole [REDACTED]

[The Sole Sponsor and the Sole [REDACTED] satisfied the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.]

The Sole Sponsor will receive a fee of HK\$[REDACTED] for acting as the sponsor for the [REDACTED].

Compliance Adviser

The Company has appointed Gram Capital Limited as the Compliance Adviser upon [REDACTED] in compliance with Rules 3A.19 and 19A.05 of the Listing Rules.

Preliminary Expenses

The Company did not incur material preliminary expense for the purpose of the Listing Rules.

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Promoters

The information of our promoters when we were established as a joint stock company is as follows:

Name of Shareholder	Number of Shares held upon our establishment	Shareholding percentage upon our establishment (%)
CSPC-NBP	51,241,785	30.5011
Yuan Qian	20,399,933	12.1428
Wuhan Caizhi	16,792,707	9.9956
Caizhi No. 2	11,620,411	6.9169
Dr. Zhou Hongfeng	10,199,921	6.0714
Huiyou Xingyao	10,142,797	6.0374
Long Star Growth	7,916,510	4.7122
Hainan Boyou	7,628,713	4.5409
Guangrui Hongxiang	7,196,835	4.2838
Dr. Zhou Pengfei	6,869,744	4.0891
Zhongheng Tongde	3,700,872	2.2029
Gongqingcheng Huiyou	3,038,340	1.8085
BGI Co-win Fund I	1,919,166	1.1424
Hainan Weifeng	1,919,166	1.1424
Guangdong Xingyao	1,620,448	0.9646
Qianshan Xinrong	1,296,358	0.7716
Sanhua Hongdao	1,247,458	0.7425
Shaoshan Hongyu	959,583	0.5712
Baiying Huizhi	959,583	0.5712
Zhuhai Shengyi	959,583	0.5712
Dr. Guo Hongwei	370,087	0.2203
Total	168,000,000	100.0000

Within the two years immediately preceding the date of this document, no cash, securities, amount or benefit has been paid, allotted or given, or has been proposed to be paid, allotted or given, to any of the promoters named above in connection with the [REDACTED] or the related transactions described in this document.

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Qualifications and Consents of Experts

The qualifications of the experts which have given opinions or advice which are contained in, or referred to in, this document are as follows:

Name of Expert	Qualifications
China Securities (International) Corporate Finance Company Limited	A licensed corporation to conduct Type 1 (dealing in securities) and Type 6 (advising on corporate finance) regulated activities (as defined under SFO)
Deloitte Touche Tohmatsu	Certified public accountants and Public Interest Entity Auditor registered in accordance with the Accounting and Financial Reporting Council Ordinance
Jingtian & Gongcheng	PRC Legal Advisor
King & Wood Mallesons	IP Legal Advisor
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant

Each of the experts listed above has given and has not withdrawn its written consent to the issue of this document with the inclusion of its report and/or letter and/or opinion and/or references to its name included herein in the form and context in which they respectively appear.

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in the Company or our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of the Group.

Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, 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 so far as applicable.

Bilingual Document

The English language and Chinese language versions of this document are being published separately, in reliance upon the exemption provided in Section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Miscellaneous

- (a) Save as disclosed in “History, Development and Corporate Structure,” within the two years preceding the date of this document, no share or loan capital of the Company or any of its subsidiary has been issued or has been agreed to be issued fully or partly paid either for cash or for a consideration other than cash;
- (b) No share or loan capital of the Company or any of its subsidiary is under option or is agreed conditionally or unconditionally to be put under option;
- (c) No founder, management or deferred shares of the Company or any of its subsidiary have been issued or have been agreed to be issued;
- (d) The Company is not presently listed on any stock exchange or traded on any trading system;
- (e) The Company has no outstanding convertible debt securities or debentures;
- (f) None of the experts listed under “– Qualifications and Consents of Experts”:
 - (i) is interested beneficially or non-beneficially in any shares in any member of the Group; or
 - (ii) has any right or option (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of the Group save in connection with the [REDACTED];
- (g) The English text of this document and the [REDACTED] shall prevail over their respective Chinese text;
- (h) There has not been any interruption in the business of the Group which may have or has had a significant effect on the financial position of the Group in the 12 months preceding the date of this document;
- (i) The Company is currently a sino-foreign investment joint stock limited company and subject to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》)⁽¹⁾;
- (j) There is no arrangement under which future dividends are waived or agreed to be waived.

(1) *The Foreign Investment Law of the PRC has become effective on January 1, 2020, and the Sino-foreign Joint Venture Law of the PRC was abolished on the same date.*

APPENDIX VII DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

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 [REDACTED];
- (b) the written consents referred to in “Appendix VI – Statutory and General Information – Other Information – Qualifications and Consents of Experts” in this document; and
- (c) a copy of each of the material contracts referred to in “Appendix VI – Statutory and General Information – Further Information about our Business – Summary of Material Contracts” in this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Stock Exchange at www.hkexnews.hk and our websites at www.yzybio.com during a period of 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the Accountants’ Report for the two years ended December 31, 2021 and 2022 prepared by Deloitte Touche Tohmatsu, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of the Group for the two years ended 31 December 2021 and 2022;
- (d) the report received from Deloitte Touche Tohmatsu on the unaudited [REDACTED] financial information of the Group, the text of which is set out in Appendix II to this document;
- (e) the legal opinion from Jingtian & Gongcheng, the Company’s PRC Legal Advisor, in respect of certain aspects of the Company;
- (f) the industry report prepared by Frost & Sullivan;
- (g) the PRC Company Law, the PRC Securities Law, the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies and the Guidelines for Articles of Association together with their unofficial English translations;
- (h) the service contracts between each of the Directors and Supervisors and the Company referred to in “Appendix VI – Statutory and General Information;”

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**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY**

- (i) the material contracts referred to in “Appendix VI – Statutory and General Information;”
- (j) the written consents referred to in “Appendix VI – Statutory and General Information;” and
- (k) the due diligence report issued by King & Wood Mallesons, our IP Legal Advisor, in respect of, among other things, the PRC intellectual property matters.