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Post Hearing Information Pack of

Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.

四川科倫博泰生物醫藥股份有限公司

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Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
四川科倫博泰生物醫藥股份有限公司

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

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levy of 0.00015% and the Stock
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[REDACTED]

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EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

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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 this document in its entirety before you decide to [REDACTED] in the [REDACTED]. There are risks associated with any [REDACTED]. Some of the risks involved in [REDACTED] in the [REDACTED] are set out in the “Risk Factors” section of this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules as we do not meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies like ours. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW

We are an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in oncology, immunology and other therapeutic areas in China and globally. As of the Latest Practicable Date, we were advancing a differentiated and clinically valuable pipeline of 33 assets, including five in pivotal trial or NDA registration-stage, nine in phase 1 or phase 2 stage and four in IND-enabling stage. We have two ADC drugs as our Core Products, namely, SKB264 and A166. SKB264 is a novel phase 3-stage TROP2 ADC positioned as a late-line monotherapy and part of early-line combination therapies for treating various advanced solid tumors, including breast cancer (BC), non-small cell lung cancer (NSCLC) and other major cancers. A166 is a differentiated NDA registration-stage HER2 ADC positioned as a late-line monotherapy to treat advanced HER2+ solid tumors.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR PIPELINE PRODUCTS, INCLUDING CORE PRODUCTS SKB264 AND A166.

The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets.

SUMMARY

Product	Target	Molecule Type	Indication (Lines of Treatment)	Preclinical/IND-enabling	Phase Ia	Phase Ib/2	Registration/ Pivotal Ph I/ Ph III	NDA Filing	NCT/CTR No.	Commercial Rights/Partners				
ADIC	TROP2	Large	TNBC (3L+) TNBC (1L) HR+/HER2- BC (2L+) EGFR-wild type (1L) and EGFR-mutant (TKI failure) NSCLC EGFR-wild type (1L) and EGFR-mutant (TKI failure) NSCLC EGFR-mutant NSCLC (TKI failure) EGFR-mutant NSCLC (1L) EGFR-wild type NSCLC (1L) and EGFR-mutant (TKI failure) NSCLC GC (2L+) OC (platinum-resistant) Solid tumors (SCLC, UC, HNSCC and EC) NPC (PD-(L)1 relapse or refractory) CC (2/3L) UC (1L) OC (2L maintenance) CRPC (2L+)	Combo with/without A167 Combo with Keytruda and/or chemo Combo with osimertinib Combo with A167 with/without platinum-based chemo	Phase Ia Phase Ib/2 Registration/ Pivotal Ph I/ Ph III	NCT05241134; CTR20210737; NCT05445908; CTR20211755; NCT04152499; CTR20210669; NCT05241134; CTR20222948; CTR202230825 NCT05351788; CTR20220980 NCT04152499; CTR20210669 NCT05051262; CTR20222948 NCT05642780; CTR20223165 CTR20212088 CTR20213396 CTR20212950 NCT05367635; CTR20220283 N/A NCT03848286; CTR20220283 NCT05294172; CTR20220691 NCT04835142; CTR20202451 NCT05268091; CTR20211547 CTR20211066 CTR20211028 NCT05387928; CTR20220985 NCT05449804; CTR20221772 CTR20202664 NCT05496426; CTR20221881 CTR20222274 CTR20221961 CTR20211808	Greater China / MSD (ex-Greater China) Global Global Global (ex-China, HK, Macau) Greater China / HARBOR (ex-Greater China) Global Greater China and part of Asia / ELLIPSES (ex-Greater China and part of Asia) Global Global Global Global Global Global Global / HARBOR (Co-development) Global							
				SKB264 ★										
				A166 ★	HER2	Large	HER2+ BC (3L+) HER2+ GC (2L+) HER2+ CRC (3L+)							Global
				SKB315 ☆	CLDN18.2	Large	Solid tumors							MSD
				Up to seven preclinical assets	/	Large	Solid tumors							MSD
				A167 ☆	PD-L1	Large	NPC (3L+)							Greater China / HARBOR (ex-Greater China)
				A140 ☆	EGFR (Biosimilar)	Large	NPC (1L) CRC ¹							Global
				A400 ☆	RET	Small	RET+ NSCLC (1L) RET+ NSCLC (2L+) RET+ MTC and other RET+ solid tumors							Global
				SKB337	PD-L1/ CTLA4	Large	RET+ inhibitor-resistant solid tumors							Global
				A289 ¹	LAG3	Large	Solid tumors							Global
				A296	STING	Small	Solid tumors (intravenous infusion) Solid tumors (intratumoral injection)							Global
				A223 ☆	JAK 1/2	Small	Rheumatoid arthritis							Global
A277	KOR	Small	Alopecia areata							Global				
SKB378	TSLP	Large	CKD-ap							Global				
SKB336	FXR/FXr	Large	Asthma Thromboembolic disorders							Global / HARBOR (Co-development)				

★ Core Products ☆ Key Products 🔑 Breakthrough Designation

Abbreviations: TNBC: triple-negative breast cancer; BC: breast cancer; GC: gastric cancer; OC: ovarian cancer; SCLC: small-cell lung cancer; UC: urothelial cancer; HNSCC: head and neck squamous cell carcinoma; EC: endometrial cancer; CRC: colorectal cancer; CRPC: castration-resistant prostate cancer; MTC: medullary thyroid cancer; CKD-ap: chronic kidney disease-associated pruritus

Notes:

- Including immunotherapy and targeted therapies; 2. No phase II clinical trial is required for biosimilar drug candidates in China; 3. CDE consultation completed; 4. We completed a phase Ia study and are conducting a phase Ib study. Based on the NMPA's approval, we also commenced a pivotal phase 2 clinical trial. Upon meeting the primary endpoint in this trial, we filed NDA for conditional approval, which is under priority review. Although we completed the study per protocol, the trial is ongoing as certain patients responsive to the drug continue with treatment. Pending consultation with the CDE, we plan to commence a confirmatory phase 3 trial in 2H 2023;
- CDE consultation ongoing; 6. A phase Ia and pivotal phase 2 clinical trial was completed. We commenced a confirmatory phase 3 trial upon consultation with the CDE; 7. Phase Ia/1b trial.

SUMMARY

Supported by three in-house developed technology platforms with proprietary know-how in ADCs, biologics (monoclonal antibodies (mAbs) and bispecific antibodies (bsAbs)) and small molecule drugs and validated by our clinical-stage drug candidates, our pipeline is diverse and synergistic in drug modalities, mechanisms, and indication coverage. Notably, we are one of the first movers and a leading developer of antibody drug conjugates (ADCs), with over a decade of accumulated experience in ADC development. We are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an integrated ADC platform, *OptiDC*. Our drug development capabilities are further bolstered by current good manufacturing practice (cGMP)-compliant, end-to-end manufacturing capabilities and a comprehensive quality control system. Furthermore, we are well-positioned to expand our commercialization infrastructure and market access, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network.

The clinical value of our pipeline and our drug development capabilities are recognized by the strategic partnerships we have forged worldwide to unlock the global market potential of key assets. To date, we have entered into nine out-license agreements, including three license and collaboration agreements with Merck Sharp & Dohme LLC (together with its affiliates, “MSD”) to develop up to nine ADC assets for cancer treatment with upfront and milestone payments totaling up to US\$11.8 billion. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical MNC. Our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world’s largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth.

Going forward, we strive to advance our pipeline towards commercialization and enhance our integrated drug development capabilities. We will continue to lead the R&D and clinical activities of our drug candidates, including, for assets out-licensed to our strategic partners, in the regions where we retain the rights to their development and commercialization. In addition, we are dedicated to optimizing our R&D platforms and developing novel technologies to support the R&D of innovative drugs. We will also continue to expand our cGMP manufacturing and quality control facilities, and enhance our in-house commercialization functionalities, to support the future launch of our pipeline assets and our goal to become a leading global biopharmaceutical company.

SUMMARY

OUR PIPELINE

Our pipeline targets the world’s prevalent or hard-to-treat cancers, such as BC, NSCLC, gastrointestinal (GI) cancers (including gastric cancer (GC) and colorectal cancer (CRC)), as well as non-oncology diseases and conditions affecting a large and underserved population. As of the Latest Practicable Date, we had established a pipeline of 14 clinical-stage drug candidates, including five in pivotal trial- or NDA registration-stage. All of these drug candidates were self-developed by the Group, other than the development that is being conducted with license and collaboration partners, as disclosed in more detail below. We have also assembled a diverse portfolio of preclinical assets, including four in IND-enabling stage, to further enrich our expanding pipeline targeting medical needs.

Our oncology franchise features diversified treatment modalities and targets different mechanisms to comprehensively treat prevalent or hard-to-treat cancers in China and worldwide, anchored by the following assets:

- **SKB264 (*sacituzumab tirumotecan*)**, one of our Core Products, is a novel TROP2 ADC targeting advanced solid tumors. Drugs that successfully target TROP2 have vast market potential as TROP2 is frequently overexpressed across a broad spectrum of cancers, especially in highly prevalent or hard-to-treat cancers such as BC, NSCLC, GC and OC. Notably, TROP2 has one of the highest overexpression rates in the lead indications of SKB264, namely BC (80%) and NSCLC (64% to 75%). BC is the most prevalent type of cancer worldwide, with TNBC and HR+/HER2- BC being the most aggressive and most prevalent subtype, respectively. Lung Cancer (LC) is the second most common cancer and the leading cause of cancer death worldwide, with NSCLC being most common subtype representing over 85% of all LC cases globally.

The global TROP2 ADC market is expected to increase from US\$0.7 billion in 2022 to US\$25.9 billion by 2030, representing a CAGR of 57.6%, while the TROP2 ADC market in China following the NMPA approval of the first TROP2 ADC in June 2022, is projected to grow from RMB0.2 billion in 2023 to RMB23.6 billion by 2030 at a CAGR of 103.0%. For more quantitative information on the drug market size, the number of patients targeted by SKB264 and the life expectancy of such patients, see “Business – Our Pipeline – Oncology Franchise – SKB264 – Market Opportunity and Competition.”

Positioned to be the first domestically developed TROP2 ADC in China, SKB264 utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window. SKB264 also demonstrated encouraging efficacy across multiple types of heavily pretreated advanced solid tumors and a potentially favorable safety profile based on preliminary clinical data from its global phase 1/2 trial. We are also exploring SKB264’s early-line potential in combination therapy. Other than SKB264, Gilead Sciences’ Trodelvy, the only approved TROP2 ADC globally, and Daiichi Sankyo’s DS-1062 were the only two TROP2 ADCs in phase 3 or beyond that target the same lead indications (TNBC, HR+/HER2- BC and NSCLC) as SKB264 as of the Latest

SUMMARY

Practicable Date. Trodelvy is positioned as a 3L+ monotherapy for TNBC and HR+/HER2- BC, and part of a 1L combination therapy for NSCLC, while DS-1062 is positioned as a 1L monotherapy for TNBC, 2L+ monotherapy for NSCLC and HR+/HER2- BC, and part of 1L combination therapies for these three indications.

Supported by its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 outside Greater China. See “Business – Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB264” for details.

We are actively advancing a multi-strategy clinical development plan to explore SKB264’s potential as a monotherapy and combination therapies to treat various advanced solid tumors, including BC, NSCLC and other major cancers. For details, see “Business – Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan.”

- **A166 (*trastuzumab botidotin*)**, another Core Product, is a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors. It is positioned to target multiple cancer indications with high prevalence and medical needs, with the potential to be one of the first domestically developed ADCs for HER2-positive (HER2+) BC in China. HER2 overexpression is widely recognized as a major driver of prevalent cancers, including BC and GI cancers, with A166’s lead indication, advanced HER2+ BC, being a major BC subtype.

China’s HER2 ADC market is expected to grow from RMB0.6 billion in 2022 to RMB8.4 billion in 2030 at a CAGR of 38.2%. For more quantitative information on the drug market size, the number of patients targeted by A166 and the life expectancy of such patients, see “Business – Our Pipeline – Oncology Franchise – A166 – Market Opportunity and Competition.”

Configured with a potent cytotoxic payload, clinically proven mAb and site-specific conjugation technology, A166 demonstrated promising efficacy in heavily pre-treated advanced HER2+ BC patients and in advanced HER2+ GC patients and a differentiated safety profile, based on preliminary results from our ongoing phase 1 dose expansion study and ongoing phase 1b trial in China. A166 has met the primary endpoints of its pivotal phase 2 trial for advanced HER2+ BC based on results from the primary analysis, which we used to submit an NDA to the NMPA in May 2023. In addition to our pivotal phase 2 trial for advanced HER2+ BC, we are exploring the therapeutic potential of A166 in multiple phase 1b clinical trials in China for other advanced HER2+ solid tumors, including GC and CRC. As of the Latest Practicable Date, there were two approved HER2 ADCs, Genentech’s Kadcyla and Daiichi Sankyo’s Enhertu, that target the same lead indication (advanced HER2+ BC) as A166 in China, with Kadcyla positioned as a 2L treatment and Enhertu as a 2L+ treatment.

SUMMARY

- **SKB315** is a novel CLDN18.2 ADC targeting advanced solid tumors. As of the Latest Practicable Date, there were no CLDN18.2-targeting therapies approved globally. Due to its selective expression in prevalent and lethal cancers that have limited effective treatments such as GC and PC, CLDN18.2 has been a promising target pursued by multiple biopharmaceutical and biotech companies for in-house development and licensing deals. In June 2022, we out-licensed the global development and commercialization rights for SKB315, currently in phase 1a clinical trial, to MSD. With a differentiated payload-linker design and an in-house developed humanized CLDN18.2 antibody, SKB315 demonstrated encouraging efficacy and safety across various preclinical *in vivo* tumor models with heterogeneous CLDN18.2 expression, indicating its promising therapeutic potential.
- **A167 (*tagitanlimab*)**, our PD-L1 mAb, is expected to be our first commercialized product and the backbone of our immunotherapy franchise, with an NDA submitted to the NMPA for recurrent or metastatic nasopharyngeal carcinoma (RM-NPC) in November 2021 and conditional marketing approval expected in the second half of 2023 or the first half of 2024. We are actively exploring A167’s potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise, beginning with two ongoing phase 2 trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC.
- **A140**, a pivotal phase 3 biosimilar of EGFR mAb cetuximab. A140 has potential to be the first cetuximab biosimilar in China with an anticipated NDA filing in the second half of 2023, providing increased accessibility and affordability for a widely used therapeutic targeting a key pathway in many cancers, starting with rat sarcoma virus (RAS) wild-type mCRC, recurrent and/or metastatic HNSCC (RM-HNSCC) and locally advanced HNSCC (LA-HNSCC). A140 demonstrated pharmacokinetic (PK) equivalence to cetuximab in a phase 1 trial, with clinical equivalence being evaluated in a pivotal phase 3 trial.
- **A400**, a phase 1/2-stage second-generation selective RET inhibitor, is positioned to be the first domestically developed selective RET inhibitor for NSCLC, medullary thyroid cancer (MTC) and other solid tumors with a high prevalence of RET alterations. We have designed A400 with a novel proprietary molecular structure to potentially address selective RET inhibitor resistance while maintaining target selectivity, efficacy and safety with reduced manufacturing cost and difficulty. Based on preliminary results from its ongoing phase 1/2 trial, A400 demonstrated promising anti-tumor efficacy in patients with advanced RET+ solid tumors. Notably, A400 also demonstrated therapeutic potential in selective RET inhibitor-resistant patients, as well as a potentially favorable safety profile differentiated from approved first-generation selective RET inhibitors. In March 2021, we granted to Ellipses, a U.K.-based international drug development company, an exclusive license to develop, manufacture and commercialize A400 outside Greater China and certain Asian countries.

SUMMARY

We will also continue to accelerate the R&D of our preclinical oncology assets. For example, we are developing over ten preclinical ADC assets with their respective targets expressed across a broad spectrum of solid tumors. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau. For details, see “Business – Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets.”

Our non-oncology franchise covers a range of diseases and conditions with large patient populations and medical needs, with a primary focus on immune-mediated diseases, including rheumatoid arthritis (RA) and alopecia areata (AA).

Our non-oncology franchise is headlined by A223, potentially one of the first small molecule JAK1/2 inhibitors developed domestically for multiple autoimmune diseases with large patient populations, including RA and AA, in China. A223 has demonstrated an encouraging safety profile in three completed trials and two ongoing trials, where most treatment-emergent adverse events (TEAEs) were mild or moderate with no incidence of black box warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated promising anti-rheumatic efficacy in moderate-to-severe RA patients. These promising clinical results indicates the potential of A223 to be an effective treatment option with improved efficacy and safety for RA. Besides RA, we also target AA, a common autoimmune disease that affected approximately 4.0 million people in China in 2022.

In addition to A223, we are also evaluating three other clinical-stage assets (A277, SKB378 and SKB336) and various preclinical assets to target indications ranging from chronic kidney disease (CKD)-associated pruritus (CKD-aP), moderate-to-severe asthma, thromboembolic disorders, to other diseases and conditions with large patient populations and medical needs. Apart from our existing assets, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCTS, OR ANY OF OUR DRUG CANDIDATES.

OUR TECHNOLOGY PLATFORMS

We have established three core platforms specializing in ADC, biologics and small molecule technologies that serve as the foundation of our discovery and development of innovative medicines for medical needs in selected disease areas, such as oncology, autoimmune diseases and metabolic diseases. These platforms cover the entire R&D process for different drug modalities and are integrated to allow cross-functional synergies at crucial

SUMMARY

stages of drug development. Our ADC platform, *OptiDC*, is supported by three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified ADC design and development know-how, and a toolbox of core ADC components. Our biologic platform serves as the foundation of our immunotherapy and targeted therapy franchises which possesses end-to-end antibody development capabilities ranging from antibody discovery and optimization to bioprocessing and scale-up manufacturing. Our small molecule platform allows us to focus on compound optimization in early-stage research, which help rationalize and accelerate our preclinical drug discovery. For details, please see “Business – Overview – Our Technology Platforms.”

OUR COMPETITIVE STRENGTHS

We believe the following competitive strengths have differentiated us from our competitors: (i) integrated ADC development platform, “*OptiDC*,” with a competitive ADC drug portfolio to address medical needs globally; (ii) comprehensive pipeline of anti-tumor drugs harnessing our multi-platform technology expertise, with strong monotherapy and combination therapy potential; (iii) well-selected non-oncology pipeline strategically targeting diseases and conditions with immense medical needs; (iv) integrated drug development capabilities across R&D, manufacturing, quality control and commercialization; (v) cross-border business development capabilities enabling collaborations and strategic partnerships; and (vi) experienced leadership backed by our Controlling Shareholder and renowned investors. For details, see “Business – Our Competitive Strengths.”

OUR DEVELOPMENT STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following development strategies: (i) advance our indication-oriented oncology pipeline; (ii) advance and expand our differentiated non-oncology drug portfolio; (iii) enhance our integrated drug development capabilities; (iv) continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline; and (v) optimize our integrated operation system to become a leading global biopharmaceutical company. For details, see “Business – Our Development Strategies.”

OUR INTEGRATED DRUG DEVELOPMENT CAPABILITIES

We have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization. Our drug development capabilities are governed by a well-established management system that covers all key business functionalities, which provides a framework for our internal teams to engage in constructive dialogue and evaluation, particularly when making critical decisions for each drug development plan. While we are primarily focused on the in-house development of our pipeline, we supplement our in-house efforts with a dynamic global business development strategy to maximize the commercial value of our pipeline in major international markets, leveraging our experience in forging strategic partnerships worldwide.

SUMMARY

Our in-house R&D capabilities, built on three technology platforms with proprietary know-how, give us control and visibility over our R&D process, reduces our reliance on CROs and enable us to ensure the quality and efficiency of our drug development programs. Our drug development capabilities are further bolstered by cGMP-compliant, end-to-end manufacturing capabilities that cover the entire development lifecycle of ADCs, including two 2,000 litre (L) single-use bioreactors, one 300 L ADC conjugation tank with a maximum annual production capacity of 40 batches of ADC drug substance and facilities for payload-linker synthesis, antibody formulation and ADC formulation, as well as a comprehensive quality control system. We are building up our commercialization infrastructure in anticipation of our late-stage drug candidates’ commercial launch in China, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network.

Our drug development capabilities are recognized by the breadth, depth and commercial value of the strategic partnerships we have forged worldwide, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. These landmark transactions speak to the quality and soundness of our capabilities in every key step of our ADC development process, from drug discovery to manufacturing and quality control. For details of our drug development capabilities, see “Business.”

LICENSE AND COLLABORATION ARRANGEMENTS

While we are primarily engaged in in-house drug development, we also believe that an open and collaborative mindset is crucial to the success of our global strategy. Along each step of our drug development plans – from drug discovery to commercialization – we proactively pursue external collaborations, licensing arrangements and other strategic partnerships to create synergies with our pipeline and technology platforms. Set forth below is a summary of our key license and collaboration agreements. For details, see “Business – Our License and Collaboration Arrangements.”

- **Collaboration with MSD.** To date, we have entered into three license and collaboration agreements with MSD to develop SKB264, SKB315 and up to nine ADC assets for cancer treatment. In May 2022, we granted to MSD an exclusive, royalty-bearing and sublicensable license to develop, use, manufacture and commercialize our TROP2 ADCs, including SKB264 (also known as “MK2870” in MSD’s portfolio) and any other TROP2 ADCs we may develop in the future, and products containing one or more such TROP2 ADCs outside Greater China. We retain the right to develop and commercialize SKB264 and other TROP2 ADCs within Greater China. Based on such retained rights, we will continue to advance our clinical development plan for SKB264 in Greater China.

In June 2022, we granted to MSD an exclusive, royalty-bearing, sublicensable license to develop, use, manufacture and commercialize SKB315 and products based on SKB315 globally. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau.

SUMMARY

- **Collaboration with Ellipses.** We granted to Ellipses an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A400, our RET inhibitor, in all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand.
- **Collaboration with Harbour BioMed.** We granted to Harbour BioMed an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A167, our PD-L1 mAb, outside Greater China. We are also jointly developing SKB378, our anti-TSLP mAb, with Harbour BioMed.

OUR COMPETITIVE LANDSCAPE

We primarily compete against large multinational pharmaceutical companies, well-established biopharmaceutical companies and specialty pharmaceutical companies that have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of indications which our drug candidates also target, especially companies involved in the research and development of ADCs. The level of competition that we face is high and we believe the following aspects are critical for us to stay competitive and relevant in this dynamic environment: (i) a strong and comprehensive drug pipeline, (ii) technology platforms validated by our clinical-stage drug candidates, (iii) integrated capabilities across all key drug development functionalities, (iv) strong cross-border business development capabilities, and (v) an experienced leadership team. See also “Business – Our Competitive Strengths.”

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business, and we are committed to the development and protection of our intellectual properties. We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 74 issued patents in China, (ii) 21 issued patents in the U.S., (iii) 52 issued patents in other jurisdictions, and (iv) 255 pending patent applications, including 100 in China, 14 in the U.S., 16 under the Patent Cooperation Treaty (PCT) and 125 in other jurisdictions. With respect to our two Core Products, SKB264 and A166, we owned five issued patents in China and eight issued patents in other jurisdictions, as well as 21 pending patent applications, including six in China, five in the U.S., three under the PCT and eight in other jurisdictions, including Europe, Canada, Japan and Hong Kong as of the Latest Practicable Date. As of the Latest Practicable Date, we were patentee of all granted patents in China relating to the structure, formulation and use of SKB264 and A166, which are considered to be material aspects of each drug. The patents granted to, or under application by, our Company cover all material aspects of our Core Products. For details, please see “Business – Intellectual Property.”

SUMMARY

SUMMARY OF KEY FINANCIAL INFORMATION

The summary of the key financial information set forth below have been derived from and should be read in conjunction with our consolidated financial statements, including the accompanying notes, set forth in the Accountants’ Report in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

Summary of Consolidated Statements of Profit or Loss

We recognized revenue of RMB32.3 million and RMB803.9 million, respectively, in the years ended December 31, 2021 and 2022, which was primarily in relation to the license and collaboration agreements we entered into. We incurred net losses during the Track Record Period as we invested significant capital into the research and development of our extensive drug pipeline, and building up our technology platforms, manufacturing facilities and other capabilities to complement and support our business. For the years ended December 31, 2021 and 2022, we had net losses of RMB889.8 million and RMB616.1 million, respectively. The decrease of our net losses from 2021 to 2022 was primarily due to the increase in revenue from the two license and collaboration agreements we entered into with MSD to develop SKB264 and SKB315.

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

	For the year ended December 31,	
	2021	2022
	<i>(RMB’000)</i>	<i>(RMB’000)</i>
Revenue	32,322	803,933
Cost of sales	(20,525)	(276,828)
Gross profit	11,797	527,105
Other net income/(expense)	34,843	(4,368)
Administrative expenses	(96,174)	(95,303)
Research and development expenses	(727,670)	(845,984)
Loss from operations	(777,204)	(418,550)
Finance costs	(112,591)	(148,814)
Loss before taxation	(889,795)	(567,364)
Income tax	–	(48,735)
Loss for the year attributable to equity shareholders of the Company	(889,795)	(616,099)

SUMMARY

Summary of Consolidated Statements of Financial Position

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Total non-current assets	514,617	660,829
Total current assets	298,341	332,316
Total current liabilities	3,444,914	4,167,361
Net current liabilities	(3,146,573)	(3,835,045)
Total assets less current liabilities	(2,631,956)	(3,174,216)
Total non-current liabilities	11,930	51,970
Net liabilities	(2,643,886)	(3,226,186)

We recorded net liabilities of RMB2,643.9 million and RMB3,226.2 million as of December 31, 2021 and 2022, respectively. The increase was primarily due to the loss for the year of RMB616.1 million we recorded in 2022, as a result of the significant capital we invested into the research and development of our extensive drug pipeline, and building up our technology platforms, manufacturing and other capabilities to complement and support our business.

We recorded net current liabilities of RMB3,146.6 million and RMB3,835.0 million as of December 31, 2021 and 2022, respectively, mainly attributable to bank loans and other borrowings of RMB2,388.0 million and RMB2,890.8 million, respectively, as of the same dates. These amounts primarily represented our borrowings from Kelun Pharmaceutical to support our operations. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. For further details, see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing – Share Subscription by Kelun Pharmaceutical” and “Financial Information – Material Related Party Transactions.”

Despite the debt-to-equity swap and the Series B Financing, we still recorded a net current liability position of RMB947.9 million as of April 30, 2023, primarily due to the shares with preferential rights we issued to the Pre-[REDACTED] Investors. However, we expect our net current liabilities position to improve significantly upon [REDACTED], as we recorded RMB1,952.3 million in financial instruments issued to [REDACTED] as of April 30, 2023. Such shares will be converted into ordinary Shares upon [REDACTED], after which they will be recorded as equity and no longer be recorded as liabilities on our statement of financial position. As such, we expect that our net current liability and net liability position will turn into net current asset and net asset position, respectively, upon [REDACTED].

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Summary of Consolidated Statements of Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the years indicated:

	For the year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Net cash used in operating activities	(485,942)	(270,847)
Net cash used in investing activities	(94,384)	(32,150)
Net cash generated from financing activities	647,316	313,452
Net increase in cash and cash equivalents	66,990	10,455
Cash and cash equivalents at beginning of year	16,189	81,793
Effect of foreign exchange rate changes	(1,386)	712
Cash and cash equivalents at the end of year	81,793	92,960

We recorded net cash used in operating activities of RMB485.9 million and RMB270.8 million for the years ended December 31, 2021 and 2022, respectively, primarily due to investments in our research and development activities. During the Track Record Period, we financed our operations primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from Series A Financing. As of April 30, 2023, the latest practicable date for determining our indebtedness, we had cash and cash equivalents of RMB1,342.2 million.

We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. As our business continues to expand, we may require further funding through equity offerings, debt financing, license and collaboration arrangements, and other sources.

Although we recorded significant net current liabilities during the Track Record Period, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses (including any production costs), for at least the next 12 months from the date of this document, taking into account (i) the recent settlement of borrowings from Kelun Pharmaceutical, as a result of which our net current liabilities decreased to RMB947.9 million as of April 30, 2023, (ii) the capital resources available to fund our operations, including existing cash and cash equivalents, payments received from our license and collaboration agreements and [REDACTED] from the [REDACTED], and (iii) our cash burn rate, which is the average monthly amount of net cash used in operating activities, payment for property, plant and equipment and payment for intangible assets. For details, see “Financial Information – Liquidity and Capital Resources – Working Capital Sufficiency.”

SUMMARY

Key Financial Ratios

The following table set forth our key financial ratios⁽¹⁾ as of the dates:

	As of December 31,	
	2021	2022
Current ratio (%)	8.7	8.0
Quick ratio (%)	7.2	6.7

Note:

(1) For details, see “Financial Information – Key Financial Ratios.”

Cash Operating Costs

The following table provides information regarding our cash operating costs for the years indicated:

	For the year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Costs relating to research and development of our Core Products		
Staff cost	51,085	109,369
Trial and testing expenses	61,769	89,665
Raw materials and others	15,046	57,256
<i>Subtotal</i>	127,900	256,290
Costs relating to research and development of our other drug candidates		
Staff cost	183,071	184,013
Trial and testing expenses	143,068	289,284
Raw materials and others	53,211	58,135
<i>Subtotal</i>	379,350	531,432
Total	507,250	787,722

SUMMARY

	For the year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Workforce employment costs ⁽¹⁾	74,258	62,490
Direct production costs ⁽²⁾	–	–
Product marketing ⁽³⁾	–	–
Non-income taxes, royalties and other governmental charges	–	–
Contingency allowances	–	–

Notes:

- (1) Workforce employment costs represent total non-research and development personnel costs mainly including salaries and benefits.
- (2) We had not commenced commercial-scale product manufacturing as of the Latest Practicable Date.
- (3) We had not commenced product sales as of the Latest Practicable Date.

SUMMARY OF MATERIAL RISK FACTORS

Our business faces risks including those set out in the section headed “Risk Factors.” As different [REDACTED] may have different interpretations and criteria when determining the significance of a risk, you should read the “Risk Factors” section in its entirety before you decide to [REDACTED] in our Company. Some of the major risks that we face include: (i) our business and prospects depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected; (ii) we may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates; (iii) we have incurred significant net losses since inception. We anticipate that we will continue to incur net losses and may fail to achieve or maintain profitability in the future; (iv) we have entered into license and collaboration agreements with third parties in the development of our drug candidates, and may seek additional licensing and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected; (v) if we are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our drug candidates may be adversely affected; (vi) the future commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients and others in the medical community; and (vii) our future success depends in part on our ability to retain our senior management, scientific employees and other qualified personnel.

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OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Kelun Pharmaceutical was directly interested in approximately 59.75% of the total issued Shares of our Company. In addition, our Employee Incentive Platforms, namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide, were directly interested in approximately 15.52% of the total issued Shares of our Company. Kelun Jingchuan, a wholly-owned subsidiary of Kelun Pharmaceutical, is the general partner of each of our Employee Incentive Platforms. As such, Kelun Pharmaceutical was entitled to exercise the voting rights attaching to the Shares held by our Employee Incentive Platforms. Therefore, as of the Latest Practicable Date, Kelun Pharmaceutical was able to exercise approximately 75.27% of the voting rights attaching to the Shares of our Company. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Kelun Pharmaceutical will be entitled to exercise approximately [REDACTED]% voting rights attaching to the Shares directly held by it and those held by our Employee Incentive Platforms. Accordingly, Kelun Pharmaceutical and the Employee Incentive Platforms will continue to be a group of Controlling Shareholders of our Company upon the completion of the [REDACTED]. Pursuant to the Rules Governing the Listing of Shares on the Shenzhen Stock Exchange (《深圳證券交易所股票上市規則》) where Kelun Pharmaceutical is listed, an “actual controller” refers to an individual or entity that can control a company by way of investment relationship, contracts or other arrangements. Mr. LIU Gexin held approximately 25.77% equity interest in Kelun Pharmaceutical as of March 31, 2023 and is deemed as the actual controller of Kelun Pharmaceutical. Therefore, Mr. LIU Gexin is able to control Kelun Pharmaceutical and exert substantial influence over it. Considering Kelun Pharmaceutical itself is able to exercise more than 30% voting power at general meetings of our Company, Mr. LIU Gexin is entitled to, through Kelun Pharmaceutical, indirectly control the exercise of more than 30% of the voting power at general meetings of our Company. As such, we also regard Mr. LIU Gexin as our Controlling Shareholder. Therefore, Kelun Pharmaceutical, the Employee Incentive Platforms and Mr. LIU Gexin are considered as a group of Controlling Shareholders of our Company.

There is a clear business delineation of business between our Group and the Remaining Kelun Group. The Remaining Kelun Group is an integrated research-driven and market-oriented pharmaceutical company primarily focusing on: (i) manufacturing of IV (intravenous) fluids solution products and antibiotics intermediates; and (ii) research and development of generic drugs. In contrast, the overall business of our Group is at the pre-commercialization stage with R&D, manufacturing and commercialization of novel drugs to address medical needs. For details, see “Relationship with Our Controlling Shareholders” in this document.

CONNECTED TRANSACTIONS

Prior to the [REDACTED], our Group has entered into certain transactions in our ordinary and usual course of business with parties who will, upon the [REDACTED], become connected persons of our Company. We will continue to engage in certain connected transactions after the [REDACTED]. For details of such one-off connected transactions and continuing connected transactions of our Company following the [REDACTED], see “Connected Transactions.”

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We have applied for, and the Stock Exchange [has granted] us, waivers from strict compliance with (i) the announcement, circular and independent Shareholders’ approval requirements under Rule 14A.105 of the Listing Rules; and (ii) the requirement of setting a monetary annual cap set out in Rule 14A.53 of the Listing Rules. For details, see “Connected Transactions.”

PRE-[REDACTED] INVESTORS

Since the establishment of our Company, we have received several rounds of equity financing from our Pre-[REDACTED] Investors. Our diverse base of Pre-[REDACTED] Investors consists Sophisticated Investors such as IDG Capital and SDIC, which held approximately 4.80% and 3.69%, respectively, of the total issued share capital of our Company as of the Latest Practicable Date. Pursuant to applicable PRC laws, the Pre-[REDACTED] Investors shall not dispose of any of the Shares held by them within 12 months following the [REDACTED]. For details of our Pre-[REDACTED] Investments, see “History and Corporate Structure – Pre-[REDACTED] Investments” in this document.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future [REDACTED] for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our [REDACTED], capital requirements, overall financial condition and contractual restrictions. As confirmed by our PRC Legal Advisor, any future profit that we make will have to be applied to make up for our historically accumulated losses in accordance with the PRC laws, after which we will be obliged to allocate 10% of our profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient profit to our statutory common reserve fund as described above. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future.

[REDACTED] STATISTICS⁽¹⁾

	Based on an [REDACTED] of HK\$[REDACTED]	Based on an [REDACTED] of HK\$[REDACTED]
[REDACTED] of our Shares ⁽²⁾	HK\$[[REDACTED] million]	HK\$[[REDACTED] million]
Unaudited [REDACTED] adjusted net tangible liabilities of the Group per Share ⁽³⁾⁽⁴⁾	HK\$[REDACTED]	HK\$[REDACTED]

SUMMARY

Notes:

- (1) All statistics in this table are on the assumption that the [REDACTED] are not exercised.
- (2) The calculation of [REDACTED] is based on [REDACTED] Shares (including the issuance of 51,255,685 Shares pursuant to a share subscription and debt-to-equity swap agreement in January 2023 and the issuance of 26,076,205 Series B Shares with certain preferential rights issued to investors in February 2023) expected to be in [REDACTED] immediately after completion of the [REDACTED].
- (3) The [REDACTED] adjusted net tangible liabilities of our Group per Share is arrived at after making the adjustments referred to in “Appendix II – Unaudited [REDACTED] Financial Information” and on the basis that [REDACTED] shares (being the outstanding 116,050,609 Shares as of December 31, 2022 and [REDACTED] H Shares to be [REDACTED] pursuant to the [REDACTED], but excluding the issuance of 51,255,685 Shares pursuant to a share subscription and debt-to-equity swap agreement in January 2023 and the issuance of 26,076,205 Series B Shares with certain preferential rights issued to investors in February 2023) were in [REDACTED] immediately following the completion of the [REDACTED] assuming the [REDACTED] had completed on December 31, 2022 without taking into account of any Shares which may be issued upon the exercise of the [REDACTED].
- (4) No adjustment has been made to reflect our any trading results or other transactions entered into subsequent to December 31, 2022, including but not limited to the issuance of 51,255,685 Shares pursuant to a share subscription and debt-to-equity swap agreement in January 2023 and the issuance of 26,076,205 Series B Shares with certain preferential rights issued to investors in February 2023. Upon [REDACTED], these preferential rights of Series B Shares will be automatically cancelled and Series B Shares will be reclassified as equity. Had such Shares been issued and the [REDACTED] been completed on December 31, 2022, the unaudited [REDACTED] adjusted net tangible assets attributable to equity shareholders of the Company would have increased by approximately RMB[REDACTED] and the unaudited [REDACTED] adjusted net tangible assets per Share would have increased by approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]).

[REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the indicative [REDACTED] range stated in this document. We currently intend to apply these [REDACTED] for the following purposes: (i) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our Core Products, namely, SKB264 and A166, including (a) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for clinical trial development and commercialization for SKB264, and (b) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for clinical trial development and commercialization A166, (ii) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our other key products, including A140, A167, A400 and A223, (iii) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the continued development of our technology platforms for ADCs, biologics and small molecules, advance our other existing pipeline assets, and explore and develop new drug candidates, (iv) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the expansion of our manufacturing capabilities and quality control system, and (v) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for working capital and other general corporate purposes. For further details, please see “Future Plans and [REDACTED].”

SUMMARY

[REDACTED]

[REDACTED] to be borne by us are estimated to be approximately HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), representing approximately [REDACTED]% of the estimate [REDACTED] from the [REDACTED] assuming no [REDACTED] are [REDACTED] pursuant to the [REDACTED]. The [REDACTED] consist of (i) [REDACTED] expenses, including [REDACTED], of approximately HK\$[REDACTED] million, and (ii) [REDACTED] expenses of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK\$[REDACTED] million, and (b) other fees and expenses of approximately HK\$[REDACTED] million. During the Track Record Period, the [REDACTED] charged to our consolidated statements of profit or loss were RMB[REDACTED] million (approximately HK\$[REDACTED] million) and the issue costs, which was recognized as prepayments and are expected to be deducted from equity upon the [REDACTED], were RMB[REDACTED] million (approximately HK\$[REDACTED] million). After the Track Record Period, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] million is expected to be accounted for as a deduction from equity upon the [REDACTED]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

Business Development

Since the end of the Track Record Period, we have continuously developed our business and continued to advance our pipeline. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets for the treatment of cancer. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple preclinical ADC assets and exclusive options to obtain additional exclusive licenses to certain other preclinical ADC assets. We retain the right to research, develop, manufacture and commercialize certain of these ADCs for China, Hong Kong and Macau. For details, see “Business – Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets.”

We received IND approvals from the FDA in November 2022 for a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors, which we commenced in December 2022 in China. In January 2023, we received IND approval from the NMPA for SKB264’s phase 2 basket study as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC, and SKB264 was granted Breakthrough Therapy Designation for EGFR-TKI failed EGFR-mutant advanced NSCLC by the NMPA. We completed our Series B Financing in February 2023.

SUMMARY

As we strive to advance our pipeline and enhance our integrated drug development capabilities, we expect that we will continue to recognize net losses in 2023, primarily because we will continue to incur significant costs and expenses in relation to our R&D activities as we carry out and expand our preclinical and clinical development programs.

Regulatory Development

On February 17, 2023, 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 stipulated that domestic companies that seek to issue securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC. 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》) (the “Notice”), 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 [REDACTED], 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.

As of the Latest Practicable Date, our Company had submitted overseas [REDACTED] application to the CSRC and obtained the letter of acceptance from the CSRC on February 17, 2023. The CSRC issued an approval letter on March 30, 2023 for the [REDACTED], the Conversion of Domestic Shares and Unlisted Foreign Shares into H Shares, and the application to [REDACTED] our H Shares on the Hong Kong Stock Exchange. Such approval is valid for 12 months. In granting such approval, the CSRC accepts no responsibility for the financial soundness of us or for the accuracy of any of the statements made or opinions expressed in this document. As advised by our PRC Legal Advisor, according to Trial Measures and the Notice, if the [REDACTED] is not completed within the validity period of the approval of the CSRC, we will be required to complete the necessary filing procedures for the [REDACTED] and the [REDACTED]. No other approvals under the PRC laws and regulations are required to be obtained for the [REDACTED] of the H Shares on the Stock Exchange.

Impact of the COVID-19 Pandemic

As of the Latest Practicable Date, we had not experienced material disruptions in our operations as a result of the COVID-19 pandemic. Although we encountered temporary slow-down in subject enrollment for certain clinical trials in China, the overall impact of the COVID-19 pandemic on our clinical activities, drug development timeline, business and results of operations has been immaterial, and especially as the COVID-19 pandemic has come under control as of the Latest Practicable Date.

SUMMARY

No Material Adverse Change

After performing due diligence work which our Directors consider appropriate and sufficient and after due and careful consideration, our Directors confirm that, except as disclosed above and up to the date of this document, there has been no material adverse change in our financial or trading position or prospects since December 31, 2022, which is the end date of the periods reported on in the Accountants’ Report included in Appendix I to this document, and there is no event since December 31, 2022 that would materially affect the information as set out in the Accountants’ Report included in Appendix I to this document.

DEFINITIONS

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

“actual controller”	the individual or entity that can control a company by way of investment relationship, contracts or other arrangements according to the Rules Governing the Listing of Shares on the Shenzhen Stock Exchange (《深圳證券交易所股票上市規則》) where Kelun Pharmaceutical, our Controlling Shareholder, is listed
“affiliate”	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
“Anling Weijian”	Anling Weijian Equity Investment (Zibo) Limited Partnership (安齡偉健股權投資(淄博)合夥企業(有限合夥)), a limited liability partnership established under the laws of the PRC on April 12, 2022 and a Pre-[REDACTED] Investor
“Articles of Association” or “Articles”	the articles of association of the Company adopted at a general meeting on February 15, 2023 and with effect from the [REDACTED], as amended from time to time, a summary of which is set out in Appendix V to this document
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Board” or “Board of Directors”	the board of Directors of our Company
“Board of Supervisors”	the board of Supervisors of our Company
“BOSC Xingling”	BOSC Xingling (Jiaxing) Equity Investment Partnership (上銀杏苓(嘉興)股權投資合夥企業), a limited liability partnership established under the laws of the PRC on November 23, 2022 and a Pre-[REDACTED] Investor

DEFINITIONS

"Business Day" or "business day"	any day (other than a Saturday, Sunday or public holiday in Hong Kong and any day on which tropical cyclone warning no. 8 or above or a black rainstorm warning signal is hoisted in Hong Kong) on which banks in Hong Kong are generally open for normal banking business
"BVI"	the British Virgin Islands

[REDACTED]

DEFINITIONS

[REDACTED]

“Chengdu Wenjiang Emerging Industry Venture”	Chengdu Wenjiang Emerging Industry Venture Capital Fund Limited Partnership (成都溫江新興產業創業投資基金合夥企業(有限合夥)), a limited liability partnership established under the laws of the PRC on February 17, 2022 and a Pre-[REDACTED] Investor
“China” or “PRC”	the People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires, references in this document to “China” and the “PRC” do not include Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“Cinda Capital”	Cinda Capital Management Limited (信達資本管理有限公司), a limited liability company established in the PRC on December 16, 2008 and a Pre-[REDACTED] Investor
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“CNIPA”	China National Intellectual Property Administration (中國國家知識產權局)
“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”, and “the Company”	Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (四川科倫博泰生物醫藥股份有限公司), a joint stock company established in the PRC with limited liability on November 22, 2016
“Company Law”	the Company Law of the PRC (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“connected transaction(s)”	has the meaning ascribed thereto under the Listing Rules
“Controlling Shareholder(s)”	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Kelun Pharmaceutical, the Employee Incentive Platforms and Mr. LIU Gexin. For further details of the Controlling Shareholders of the Company, see “Relationship with Our Controlling Shareholders”
“Conversion of Domestic Shares and Unlisted Foreign Shares into H Shares”	the conversion of 19,620,539 Domestic Shares and 18,623,632 Unlisted Foreign Shares in aggregate into H Shares on a one-for-one basis upon the completion of [REDACTED]. Such conversion of Domestic Shares and Unlisted Foreign Shares into H Shares has been approved by the CSRC on March 30, 2023 and an application for H Shares to be [REDACTED] on the Stock Exchange has been made to the [REDACTED] Committee
“Core Product(s)”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Products refer to SKB264 and A166
“COVID-19”	a viral respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
“CSDC”	China Securities Depository and Clearing Co., Ltd. (中國證券登記結算有限責任公司)
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會), a regulatory body responsible for the supervision and regulation of the PRC national securities markets

DEFINITIONS

“Director(s)”	the director(s) of our Company, including all executive, non-executive and independent non-executive directors
“Domestic Share(s)”	ordinary shares in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in Renminbi
“EIT”	enterprise income tax
“EIT Law”	the 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
“Ellipses”	Ellipses Pharma Limited, a U.K.-based international drug development company focused on the development of innovative cancer treatments
“Employee Incentive Platforms”	Kelun Huicai, Kelun Huide, Kelun Huineng and Kelun Huizhi
“Employee Incentive Scheme”	the employee incentive scheme adopted and approved by our Company, a summary of the principal terms of which is set forth in Appendix VII – Statutory and General Information – D. Employee Incentive Scheme
“EU”	European Union
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“FDA”	the United States Food and Drug Administration
“FIIF”	Future Industry Investment Fund Phase II (Limited Partnership) (先進製造產業投資基金二期(有限合夥)), a limited liability partnership under the laws of the PRC on June 18, 2019 and a Pre-[REDACTED] Investor
“FIL”	Foreign Investment Law of the PRC (中華人民共和國外商投資法)
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market, research and consulting company

DEFINITIONS

“Frost & Sullivan Report” the report commissioned by the Company and independently prepared by Frost & Sullivan, a summary of which is set forth in the section headed “Industry Overview” in this document

[REDACTED]

“GMP” the Good Manufacturing Practice of Medical Devices (《醫療器械生產質量管理規範》)

“Greater China” the PRC, the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan

[REDACTED]

“Group”, “we” or “us” our Company and all of our subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of its present subsidiaries, the businesses operated by such subsidiaries or their predecessors (as the case may be)

“Gygnus Real” Gygnus Real Company Limited, a limited liability company incorporated in the BVI on March 16, 2022 and a Pre-[REDACTED] Investor

“Harbour BioMed” Harbour BioMed Therapeutics Limited, an indirect wholly owned subsidiary of HBM Holdings Limited, a company listed on the Stock Exchange (stock code: 02142)

“HK\$” or “Hong Kong dollars” Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

[REDACTED]

DEFINITIONS

“Hong Kong” the Hong Kong Special Administrative Region of the PRC

[REDACTED]

“H Share(s)” overseas [REDACTED] foreign share(s) in our ordinary share capital, with nominal value of RMB1.00 each, which are to be [REDACTED] for and traded in HK dollars, and for which an application has been made for [REDACTED] and [REDACTED] on the Stock Exchange

[REDACTED]

“IASB” International Accounting Standards Board

“IFRS” the International Financial Reporting Standards, which as collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards and Interpretations issued by the IASB

DEFINITIONS

“Independent Third Party(ies)” an individual or a company which, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is not a connected person of the Company within the meaning of the Listing Rules

[REDACTED]

DEFINITIONS

“Joint Sponsors”	Goldman Sachs (Asia) L.L.C. and CITIC Securities (Hong Kong) Limited
“Kelun-Biotech Research Center”	Sichuan Kelun-Biotech Targeted Biologics Engineering Research Center Co., Ltd. (四川科倫博泰生物靶向藥物工程研究中心有限公司), a limited liability company established under the laws of PRC on March 30, 2023 and is a wholly-owned subsidiary our Company
“Kelun Group”	Kelun Pharmaceutical and all of its subsidiaries
“Kelun Huicai”	Chengdu Kelun Huicai Enterprise Management Center Limited Partnership (成都科倫匯才企業管理中心(有限合夥)), a limited partnership established in the PRC on August 26, 2016, of which Kelun Jingchuan is the sole general partner, one of our Employee Incentive Platforms
“Kelun Huide”	Chengdu Kelun Huide Enterprise Management Center Limited Partnership (成都科倫匯德企業管理中心(有限合夥)), a limited partnership established in the PRC on August 26, 2016, of which Kelun Jingchuan is the sole general partner, one of our Employee Incentive Platforms
“Kelun Huineng”	Chengdu Kelun Huineng Enterprise Management Center Limited Partnership (成都科倫匯能企業管理中心(有限合夥)), a limited partnership established in the PRC on August 26, 2016, of which Kelun Jingchuan is the sole general partner, one of our Employee Incentive Platforms
“Kelun Huizhi”	Chengdu Kelun Huizhi Enterprise Management Center Limited Partnership (成都科倫匯智企業管理中心(有限合夥)), a limited partnership established in the PRC on August 26, 2016, of which Kelun Jingchuan is the sole general partner, one of our Employee Incentive Platforms
“Kelun Jingchuan”	Chengdu Kelun Jingchuan Technology Co., Ltd. (成都科倫晶川科技有限公司), a limited liability company established under the laws of PRC on August 17, 2016 and is a wholly-owned subsidiary of Kelun Pharmaceutical

DEFINITIONS

“Kelun Pharmaceutical”	Sichuan Kelun Pharmaceutical Co., Ltd. (四川科倫藥業股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002422), one of our Controlling Shareholders
“Kelun Medicine & Trade”	Sichuan Kelun Medicine & Trade Group Co. Ltd. (四川科倫醫藥貿易集團有限公司), an associate of Mr. Liu Sichuan and a connected person to us
“Kelun Medicine & Trade Group”	Kelun Medicine & Trade and all of its subsidiaries
“Kelun Research Institute”	Sichuan Kelun Pharmaceutical Research Institute Co., Ltd. (四川科倫藥物研究院有限公司), a limited liability company established under the laws of PRC on October 16, 1998 and is a wholly-owned subsidiary of Kelun Pharmaceutical
“Kexin Lunda”	Guangxi Kexin Lunda Investment Limited Partnership (廣西科信倫達投資合夥企業(有限合夥)), a limited liability partnership established under the laws of the PRC on December 27, 2022 and a Pre-[REDACTED] Investor
“KLUS PHARMA”	KLUS PHARMA INC., a corporation with limited liability incorporated in the State of New Jersey, the United States on October 31, 2014 and a wholly-owned subsidiary of our Company
“Latest Practicable Date”	May 26, 2023, being the latest practicable date for the purpose of ascertaining certain information in this document prior to its publication
“LAV Kecheng”	LAV Kecheng Hong Kong Limited, a company incorporated in Hong Kong with limited liability on March 12, 2021 and a Pre-[REDACTED] Investor
“Leyue Capital”	Leyue Capital Limited, a company incorporated in Hong Kong with limited liability on September 2, 2014 and a Pre-[REDACTED] Investor
	[REDACTED]
“Listing Committee”	the Listing Committee of the Stock Exchange

DEFINITIONS

[REDACTED]

“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
“Longyi Technology”	Chengdu Longyi Technology Co., Ltd. (成都隆一科技有限責任公司), a limited liability company established in the PRC on March 2, 2016 and a Pre-[REDACTED] Investor
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange, which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange
“MNC”	multinational corporation
“MOHRSS”	Ministry of Human Resources and Social Security of PRC
“MSD”	MERCK SHARP & DOHME LLC, a New Jersey limited liability company and a Pre-[REDACTED] Investor. MSD is a wholly-owned subsidiary of Merck & Co., Inc., a company listed on the New York Stock Exchange (stock code: MRK)
“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)
“NHSA”	the National Healthcare Security Administration (國家醫療保障局)
“Ningbo Daoyi”	Ningbo Daoyi Enterprise Consulting Management Co., Ltd. (寧波道奕企業諮詢管理有限公司), a limited liability company established in the PRC on April 21, 2020 and a Pre-[REDACTED] Investor
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)

DEFINITIONS

“NPC” the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

“NRDL” National Reimbursement Drug List of China

[REDACTED]

“PBOC” the People’s Bank of China (中國人民銀行), the central bank of the PRC

“PRC Legal Advisor” King & Wood Mallesons, PRC legal advisor to our Company

DEFINITIONS

“PRC Securities Law”	the Securities Law of the PRC (《中華人民共和國證券法》), as enacted by the 6th meeting of the 9th Standing Committee of the NPC on December 29, 1998 and became effective on July 1, 1999, as amended, supplemented or otherwise modified from time to time
“Pre-[REDACTED] Investment(s)”	the pre-[REDACTED] investments in our Company undertaken by the Pre-[REDACTED] Investors, details of which are set out in the section headed “History and Corporate Structure – Pre-[REDACTED] Investments” in this document
“Pre-[REDACTED] Investor(s)”	the investors of Pre-[REDACTED] Investments
	[REDACTED]
“document”	this document being issued in connection with the Hong Kong [REDACTED]
“QIBs”	a qualified institutional buyer within the meaning of Rule 144A
“R&D”	research and development
“Regulation S”	Regulation S under the U.S. Securities Act
“Remaining Kelun Group”	Kelun Pharmaceutical and its subsidiaries, excluding our Group
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAMR”	State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“SAT”	State Administration of Taxation (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
“Series A Investors”	Wealthy Linkage, FIIF, LAV Kecheng, Suzhou Likang and Gao Ling Liangheng
“Series B Investors”	MSD, Wealthy Linkage, FIIF, Leyue Capital, Kexin Lunda, Cinda Capital, Gygnus Real, BOSCO Xingling, Chengdu Wenjiang Emerging Industry Venture, Wutong Juke, Anling Weijian, ZHOU Youcai and Longyi Technology
“SFC”	the Securities and Futures Commission of Hong Kong
“Share(s)”	shares in the share capital of our Company, with a nominal value of RMB1.00 each, comprising Domestic Shares, Unlisted Foreign Shares and H Shares
“Shareholder(s)”	holders of our Shares
“Sichuan Konas”	Sichuan Konas Pharmaceutical Co., Ltd. (四川科納斯製藥有限公司), a limited liability company established in the PRC on September 30, 2016 and a wholly-owned subsidiary of our Company
“Spin-off Rules”	the Listed Companies Spin-off Rules (for Trial Implementation) (《上市公司分拆規則(試行)》) promulgated by the CSRC on January 5, 2022
	[REDACTED]
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchange and Clearing Limited
“subsidiary(ies)”	has the meaning ascribed thereto in section 15 of the Companies Ordinance
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	supervisor(s) of our Company

DEFINITIONS

“Suzhou Likang”	Suzhou Likang Equity Investment Center (Limited Partnership) (蘇州禮康股權投資中心(有限合夥)), a limited liability partnership established under the laws of the PRC on December 18, 2018 and a Pre-[REDACTED] Investor
“Takeovers Code”	the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Track Record Period”	the period comprising the two years ended December 31, 2021 and 2022
	[REDACTED]
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Unlisted Foreign Share(s)”	unlisted ordinary Share(s) issued by the Company, with a nominal value of RMB1.00 each, which are subscribed for in a currency other than RMB
“U.S. dollars”, “US\$” or “USD”	United States dollars, 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
“VAT”	value added tax
“Wealthy Linkage”	Wealthy Linkage Limited, a company incorporated in Hong Kong with limited liability on August 31, 2018 and a Pre-[REDACTED] Investor

[REDACTED]

DEFINITIONS

[REDACTED]

“Wutong Juke”	Chengdu Wutong Juke Enterprise Management Limited Partnership (成都梧桐聚科企業管理合夥企業(有限合夥)), a limited liability partnership established under the laws of the PRC on December 19, 2022 and a Pre-[REDACTED] Investor
“Yunqi Xinneng”	Shenzhen Yunqi Xinneng Venture Investment Center Limited Partnership (深圳雲起欣能創業投資中心(有限合夥)), a limited liability partnership established under the laws of the PRC on August 4, 2022 and an ex-investor which had participated in Series B Financing and subsequently transferred its subscription to ZHOU Youcai (周有財), the sole limited partner of Yunqi Xinneng
“Gao Ling Liangheng”	Zhuhai Liangheng Equity Investment Partnership (Limited Partnership) (珠海良恒股權投資合夥企業(有限合夥)), a limited liability partnership established on March 1, 2021 under the laws of the PRC on and a Pre-[REDACTED] Investor
“%”	per cent

Certain amounts and percentage figures included in this document have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them.

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

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.

GLOSSARY OF TECHNICAL TERMS

In this document, unless the context otherwise requires, explanations and definitions of certain terms used in this document in connection with our Company and our business shall have the meanings set out below. The terms and their meanings may not always correspond to standard industry meaning or usage of these terms.

“AA”	alopecia areata, a common, distressing autoimmune disease in which immune cells in the body attack hair follicles, causing hair loss
“ACR20”	American College of Rheumatology 20 response criteria, a widely accepted efficacy measure for RA clinical trials, which is defined as a $\geq 20\%$ improvement in a core set of RA disease activity measures, including tender joint count, swollen joint count, as well as certain patient and physician assessments of global disease activity
“ACR50”	American College of Rheumatology 50 response criteria, a widely accepted efficacy measure for RA clinical trials, which is defined as a $\geq 50\%$ improvement in a core set of RA disease activity measures, including tender joint count, swollen joint count, as well as certain patient and physician assessments of global disease activity
“ADA”	anti-drug antibody, an antibody produced by the immune system against a biologic. ADAs may adversely affect the efficacy and safety of the biologic
“ADC”	antibody drug conjugate, a class of biopharmaceutical drugs that comprise an antibody conjugated to a payload molecule, typically a cytotoxic agent, via a chemical linker
“ADCC”	antibody dependent cell-mediated cytotoxicity or antibody-dependent cellular cytotoxicity, a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell, whose membrane-surface antigens have been bound by specific antibodies
“ADCP”	antibody-dependent cell-mediated phagocytosis, an immunological mechanism of elimination in which a phagocytic immune cell is engaged by antibody to engulf and degrade antibody-bound target such as a tumor cell

GLOSSARY OF TECHNICAL TERMS

“AE”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrence in a patient or subject receiving a drug or other pharmaceutical product in a clinical trial and which does not necessarily have a causal relationship with the treatment
“APC”	antigen-presenting cell, belongs to a heterogeneous group of immune cells that mediate cellular immune response by processing and presenting antigens for recognition by certain lymphocytes
“AUC”	area under the curve, a pharmacokinetic parameter that measures the body exposure to a drug, i.e., how much drug reaches a person’s bloodstream in a given period of time after a dose is given
“AUC _{0-∞} ”	area under the concentration-time curve from the first time point measured (0) extrapolated to infinity (∞), a pharmacokinetic parameter that describes the total drug exposure across time
“AUC _{0-t} ”	area under the concentration-time curve from the first time point measured (0) to the last time point measured (t), a pharmacokinetic parameter that describes the observed drug exposure
“basket study”	involves a single investigational drug or drug combination that is studied across multiple populations defined by disease stage, histology, number of prior therapies, genetic or other biomarkers, or demographic characteristics
“BC”	breast cancer
“biomarker”	a naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease, etc. can be identified
“biosimilar”	a biosimilar refers to a therapeutic biological product that is similar in quality, safety, and efficacy to an approved registered reference product “reference drug”
“bispecific ADCs” or “bsADCs”	a novel type of ADCs in which the payload molecule is conjugated to a bispecific antibody which confers targeting ability against two different antigens

GLOSSARY OF TECHNICAL TERMS

“bispecific antibody” or “bsAb”	antibody that combines two antigen-recognizing elements into a single construct, able to bind to two different antigens at the same time
“BLA”	biologics license application
“black box warning”	is the highest safety-related warning (also known as “boxed warning”) issued by the FDA that appears on the package insert of a certain prescription drug to alert consumers about the significant risk of serious or life-threatening side effects of the drug
“BRCA”	breast cancer susceptibility gene, of which there are two types, i.e., BRCA1 and BRCA2. BRCA genes are tumor suppressor genes that encode proteins responsible for repairing DNA. Deleterious BRCA mutations contribute to an increased risk of various types of cancers such as breast cancer and ovarian cancer
“Breakthrough Therapy Designation”	a designation added to the amended PRC Drug Registration Regulation (《藥品註冊管理辦法》), which went into effect on July 1, 2020. The Breakthrough Therapy Designation process is designed to expedite the development and review of therapies intended for the treatment of serious diseases for which there is no effective treatment and where preliminary evidence indicates the therapy may demonstrate a substantial improvement over available treatment options
“bystander effect”	a cytotoxic effect that occurs when the cytotoxic payload from an ADC is released either from the target cell following internalization and degradation of the ADC or after cleavage within the extracellular space, resulting in the payload being taken up by and killing surrounding cells that may or may not express the ADC target antigen
“CADD”	computer-aided drug design, the use of computers (workstations) to aid in the creation, modification, analysis, or optimization of novel compounds or biologics
“CC”	cervical cancer

GLOSSARY OF TECHNICAL TERMS

“CDC”	complement-dependent cytotoxicity, the mechanism by which antibody-bound target cells recruit and activate components of the complement cascade, leading to the formation of a membrane attack complex on the cell surface and subsequent cell lysis
“cell-line derived xenograft model” or “CDX model”	a model used for the research and testing of anti-cancer therapies. Human tumor samples are cultured as cell lines and implanted into mouse models to test the efficacy of anti-tumor compounds in vivo
“cGMP”	current good manufacturing practice. It assures proper design, monitoring, and control of manufacturing processes and facilities
“chemotherapy” or “chemo”	a drug treatment that uses cytotoxic chemicals to kill fast-growing cells in a patient’s body. It is most often used as a cancer treatment as cancer cells grow and multiply much faster than most cells in the body
“CKD-aP”	chronic kidney disease (CKD)-associated pruritus, common condition of intense and systemic itchy skin in patients with CKD, a slowly progressive (months to years) decline in the kidneys’ ability to filter metabolic waste products from the blood
“CLDN18.2”	claudin 18.2, a member of the Claudin protein family, located on the surface of cell membrane, and normally expressed at a low level in differentiated epithelial cells of gastric mucosa
“C _{max} ”	maximum plasma concentration, a pharmacokinetic parameter that measures the highest concentration of a drug in the blood, cerebrospinal fluid, or target organ after a dose is given
“CMC”	chemistry, manufacturing and controls, also commonly referred to as process development, which covers the various procedures used to assess the physical and chemical characteristics of drug products, and to ensure their quality and consistency during manufacturing

GLOSSARY OF TECHNICAL TERMS

“CMO”	contract manufacturing organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of manufacturing services outsourced on a contract basis
“CNS”	central nervous system
“cohort”	a group of patients as part of a clinical trial who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	a treatment that uses more than one medication or modality
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRC”	colorectal cancer, a type of cancer arising from the colon or rectum
“CRPC”	castration-resistant prostate cancer
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4, a protein expressed on all T cells and functions as an immune checkpoint that downregulates immune responses. It is one of the immune checkpoints commonly exploited by tumor cells to evade anti-tumor immune response
“cytotoxic”	toxic to living cells
“DAR”	drug-to-antibody ratio, the average number of drugs conjugated to the antibodies
“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)

GLOSSARY OF TECHNICAL TERMS

“DOR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“dose escalation study”	a phase in a clinical trial in where different dose of an agent (e.g. a drug) are tested against each other to establish which dose works best and/or is least harmful
“dose expansion study”	a trial enrolling additional participants to typically further evaluate efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics
“EC”	endometrial cancer
“EGFR”	epidermal growth factor receptor
“ESRD”	end-stage renal disease, that is a disease stage requiring dialysis or kidney transplant for survival due to insufficient kidney function
“Fc region”	fragment crystallizable region, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
“first-line” or “1L”	with respect to any disease, the first line treatment, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“five-year survival rate”	a type of survival rate for estimating the prognosis of a particular disease, normally calculated from the point of diagnosis
“FXI/FXIa”	factor XI, a type of blood protein playing a role in aiding the blood to clot. Factor XIa, one of the enzymes of the coagulation cascade. FXI is the zymogen form of FXIa
“GC”	gastric cancer
“GI cancers”	gastrointestinal cancer, malignant conditions of the gastrointestinal tract (GI tract) and accessory organs of digestion, including the esophagus, stomach, biliary system, pancreas, small intestine, large intestine, rectum and anus

GLOSSARY OF TECHNICAL TERMS

“head-to-head trial”	a trial designed to evaluate an investigational medicine compared to an existing standard of care
“HCC”	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver
“HER2”	human epidermal growth factor receptor 2, the overexpression of which promotes the development of various types of cancer such as breast cancer, gastric cancer and colorectal cancer
“HNSCC”	head and neck squamous cell carcinoma
“HR”	hormone receptor
“immune checkpoint inhibitor(s)”	a type of immunotherapy that blocks proteins called immune checkpoints that prevent the immune system from attacking the cancer cells
“ILD”	interstitial lung disease, a group of lung conditions that causes scarring or fibrosis of lung tissues
“IRC”	an independent review committee
“immunostimulatory ADCs” or “iADCs”	a novel form of ADCs to activate anti-tumor immune response on top of conventional tumor-directed cytotoxin delivery
“immunotherapy”	a type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases
“IC ₅₀ ”	the half maximal inhibitory concentration, which is a measure of the potency of a substance in inhibiting a specific biological or biochemical function. The lower the IC ₅₀ value, the more potent the substance
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.

GLOSSARY OF TECHNICAL TERMS

“in vivo”	Latin for “within the living”, studies in vivo are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done in vitro
“in vitro”	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
“JAK1/2”	Janus kinase 1 or Janus kinase 2, two members of Janus kinase family of intracellular, non-receptor enzymes that transduce cytokine-mediated signals via the JAK-signal transducers and activators of transcription pathway, a key signaling route through which cytokines transduce extracellular signals to induce inflammation, control immune response, and orchestrate hematopoiesis
“KOL”	key opinion leaders, influencers and trusted persons who have expert product knowledge and influence in a respective field and are an important part of burgeoning industries and businesses in China, including biotech/pharmaceutical industries
“KOR”	kappa-opioid receptor, one major type of opioid receptor, which are ubiquitously distributed in the central and peripheral nervous system, with a major role in the induction, transmission and perception of sensations such as pain and itch
“LA-HNSCC”	locally advanced head and neck squamous cell carcinoma
“LAG-3”	lymphocyte-activation gene 3, which is an immune checkpoint receptor protein found on the cell surface of effector T cells, NK cells, B cells and plasmacytoid dendritic cells
“LC”	lung cancer
“linker”	one of the three core components of an ADC. A linker connects the antibody and payload via chemical bonds
“mCRC”	metastatic colorectal cancer

GLOSSARY OF TECHNICAL TERMS

“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
“monoclonal antibody” or “mAb”	an antibody generated by identical immune cells that are all clones of the same parent cell
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“MTC”	medullary thyroid cancer
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“NDA”	new drug application
“NK cell”	natural killer cell, a type of immune cell that has granules (small particles) with enzymes that can kill tumor cells or cells infected with a virus
“NPC”	nasopharyngeal cancer
“NSCLC”	non-small-cell lung cancer
“OC”	ovarian cancer
“off-target toxicity”	adverse effects that occur when a drug binds to target other than those for which the drug was designed to bind
“oncology”	a branch of medicine that deals with tumors, including study of their development, diagnosis, treatment and prevention
“on-target off-tumor toxicity”	adverse effect of a therapy on normal tissues that have shared expression of the targeted antigen with tumor cells
“ORR”	proportion of patients with a complete response or partial response to treatment

GLOSSARY OF TECHNICAL TERMS

“OS” or “overall survival”	the length of time from either the date of diagnosis or the start of treatment for a disease that patients diagnosed with the disease are still alive, used in clinical trials as a measurement of a drug’s effectiveness
“payload”	one of the three core components of an ADC. Payloads are conventionally highly active and cytotoxic molecules attached to an antibody via a chemical linker, with non-cytotoxic payloads recently emerged as novel ADC strategies for oncology and non-oncology indications
“PARP”	poly (ADP ribose) polymerase, a family of proteins primarily involved in DNA replication and transcriptional regulation, which plays an important role in cell survival in response to DNA damage
“PC”	pancreatic cancer
“PCC”	preclinical candidates
“PDX model”	a model of cancer where the tissue or cells from a patient’s tumor are implanted into an immunodeficient or humanized mouse to evaluate the natural growth of cancer, its monitoring, and corresponding treatment for the original patient
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PD-L1”	PD-1 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
“PD-(L)1”	referring to PD-1 or PD-L1
“PFS”	the length of time during and after the treatment that a patient lives without the disease getting worse
“phase 1 clinical trial”	a 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

GLOSSARY OF TECHNICAL TERMS

“phase 2 clinical trial”	a 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 3 clinical trial”	a 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
“pivotal trial”	a clinical trial to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“pharmacokinetics” or “PK”	a measurement of how fast and how completely the drug is absorbed into animal or human body, and the distribution, metabolism, and excretion of drugs in animal or human body
“platinum-based chemotherapy”	chemotherapy containing platinum complexes, which is used to treat multiple types of cancers
“PR”	partial response, referring 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 RECIST
“proof-of-concept trial”	early clinical drug development during which the objective is to obtain an initial evaluation of the potential efficacy of a treatment
“PROTAC”	proteolysis targeting chimera, a heterobifunctional small molecule composed of two active domains and a linker, capable of removing specific unwanted proteins
“Q2W” and “Q3W”	dosing frequency, referring to “once every two weeks” and “once every three weeks,” respectively

GLOSSARY OF TECHNICAL TERMS

“RA”	rheumatoid arthritis, a prevalent chronic systemic autoimmune disease in which joints are inflamed, resulting in swelling and pain. As the disease progresses, gradual bone erosion and joint destruction may occur, significantly compromising the quality of life of patients
“RANO”	Response Assessment in Neuro-oncology, referring to recommended criteria for standardized tumor response and progression assessment in clinical trials involving brain metastases
“RAS”	rat sarcoma virus, a family of genes that encode proteins that control cell growth and cell death. RAS genes are among the most common oncogenes in human cancer
“randomized controlled trial”	a study design that randomly assigns participants into a treatment group or a control group
“radionuclide drug conjugates”	A novel form of drug conjugates composed of an antibody linked to a radionuclide, a radioactive isotope, via a chemical linker
“RECIST”	Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve (“respond”), stay the same (“stabilize”), or worsen (“progress”) during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment of Cancer, National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Now the majority of clinical trials worldwide evaluating cancer treatments for objective response in solid tumors use RECIST. These criteria were developed and published in February 2000, and subsequently updated in 2009
“RET”	rearranged during transfection, a proto-oncogene, i.e., a gene that promotes cancer formation when altered by mutations or rearrangements. RET alterations have been reported to be a major oncogenic driver in about 2% of all cancers, most notably in NSCLC and MTC
“RM-HNSCC”	recurrent and/or metastatic head and neck squamous cell carcinoma

GLOSSARY OF TECHNICAL TERMS

“RP2D”	recommended phase 2 dose, usually the highest dose with acceptable toxicity, usually defined as the dose level producing around 20% of dose-limiting toxicity
“RTKs”	receptor tyrosine kinases, a type of cell surface receptors that play an important role in a variety of cellular processes, including cell-to-cell communication and cell division, maturation, movement, metabolism, and survival. Drugs that block mutant RTKs, which may cause abnormal cell growth, are being used to treat certain types of cancers
“SAE”	serious adverse event, 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
“SCLC”	small-cell lung cancer
“SD”	stable disease. In oncology, it refers to cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are given when initial treatments (first-line therapy) do not work, or stop working
“solid tumors”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are carcinomas (cancers that begin in the lining layer (epithelial cells) of organs) and lymphomas (cancers that begin in lymphocytes where lymphomas occur when lymphocytes change and grow out of control)
“standard of care”	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals

GLOSSARY OF TECHNICAL TERMS

“STING”	stimulator of interferon genes, a signaling molecule associated with the endoplasmic reticulum, which is essential for controlling the transcription of numerous host defence genes and plays a key role in innate immunity
“TAA”	tumor-associated antigen, an antigen with elevated level on tumor cells and lower levels on normal cells
“TAA-IO bsAbs”	tumor-associated-immuno-oncology bispecific antibodies, a type of bispecific antibodies with dual targeting ability against a certain tumor-associated antigen on tumor cells and a certain immune-oncology antigen involved in anti-tumor immune response, such as an immune checkpoint protein
“targeted therapy”	a major type of treatment modalities that works by targeting a particular molecule or molecules implicated in or essential to the pathogenesis of cancer and non-oncology indications, including but not limited to small molecule drugs and monoclonal antibodies
“TC”	thyroid cancer
“T cell”	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
“TEAE”	Treatment-emergent adverse event, either an adverse event with onset after the initiation of the study medication or an adverse event with onset before study medication that worsened in severity after the initiation of study medication
“TGI”	tumor growth inhibition, a medical term that measures the reduction in growth of tumors or tumor cells by a certain treatment
“therapeutic window”	the range of drug dosages which can treat disease effectively without having toxic effects, or the time interval during which a particular therapy can be given safely and effectively

GLOSSARY OF TECHNICAL TERMS

“third-line” or “3L”	with respect to any disease, the therapy or therapies that are given when both initial treatment (first-line therapy) and subsequent treatment (second-line therapy) do not work, or stop working
“TKI”	tyrosine kinase inhibitor, a type of targeted therapy that inhibit tyrosine kinases
“TNBC”	triple-negative breast cancer
“TRAE”	treatment-related adverse event, which is an adverse event that in the investigator’s opinion may have been caused by the study medication with reasonable possibility
“TROP2”	human trophoblast cell-surface antigen 2, which is a transmembrane protein frequently over-expressed in many types of solid tumors
“TSLP”	thymic stromal lymphopoietin, an important cytokine implicated in the pathophysiology of asthma as a key orchestrator of the underlying inflammation
“TTR”	time to response, the time from the start of treatment to the first objective tumor response (tumor shrinkage of $\geq 30\%$) observed for patients who achieved a CR or PR
“TTP”	time to tumor progression, the length of time from the date of diagnosis of the tumor or the start of treatment until the disease starts to get worse or spread to other parts of the body. In a clinical trial, measuring the TTP is one way to see how well a new treatment works
“UC”	urothelial cancer
“VEGF”	vascular endothelial growth factor, a protein that stimulates the formation of blood vessels
“wild type”	a strain, gene, or characteristic which prevails among individuals in natural conditions, as distinct from an atypical mutant type

FORWARD-LOOKING STATEMENTS

This document contains certain forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “going forward,” “intend,” “may,” “might,” “ought to,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change.

These statements are subject to certain risks, uncertainties and assumptions, including the risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing us which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- the timing of initiation and completion, and the progress of our preclinical studies and clinical trials;
- the timing and likelihood of regulatory filings and approvals, such as INDs and NDAs;
- our license and collaboration agreements;
- the commercialization strategies and pricing policy of our drug candidates;
- the market opportunities of our drug candidates;
- our ability to attract and retain senior management and key employees;
- our operations and business prospects;
- our business strategies and plans to achieve these strategies;
- industry trends and competition;
- our ability to control costs and expenses;
- our ability to defend our intellectual rights and protect confidentiality;
- our dividend policy;
- changes or volatility in interest rates, foreign exchange rates, equity prices, trading volumes, commodity prices and overall market trends;

FORWARD-LOOKING STATEMENTS

- capital market developments;
- the actions and developments of our competitors;
- changes to regulatory and operating conditions in the industry and markets in which we operate; and
- all other risks and uncertainties described in the section headed “Risk Factors” in this document.

Subject to the requirements of applicable laws, rules and regulations, we do not have any and undertake no obligation to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. As a result of these and other risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect or at all. Accordingly, the forward-looking statements are not a guarantee of future performance and you should not place undue reliance on any forward-looking information. Moreover, the inclusion of forward-looking statements should not be regarded as representations by us that our plans and objectives will be achieved or realized. All forward-looking statements in this document are qualified by reference to the cautionary statements in this section. In this document, statements of or references to our intentions or those of the Directors are made as of the date of this document. Any such information may change in light of future developments.

RISK FACTORS

An [REDACTED] in our H Shares involves various risks. You should carefully consider all the information in this document and in particular the risks and uncertainties described below before making an [REDACTED] in our H Shares.

The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] of our H Shares could decline and you may lose all or part of your [REDACTED]. You should seek professional advice from your relevant advisers regarding your prospective [REDACTED] in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and prospects depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected.

Our revenue and profitability are substantially dependent on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and capital resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future.

The success of our drug candidates will depend on a number of factors, including:

- favorable safety and efficacy data from our preclinical studies and clinical trials;
- sufficient resources to discover or acquire additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- successful enrollment of patients in, and completion of, clinical trials;
- sufficient supplies of drug products that are either used in combination or in comparison with our drug candidates;
- modifications to the protocols, which may delay the clinical program, regulatory approvals or commercialization, and require us to supplement, modify, or withdraw and refile our applications for regulatory approvals;

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- the performance by CROs or other third parties we engage to conduct clinical trials and preclinical studies and their compliance with our protocols and applicable laws without damaging or compromising the integrity of the resulting data;
- the capabilities and competence of our collaborators;
- the success of clinical trials conducted by, or jointly with, our collaborators;
- receipt of regulatory approvals;
- strong commercial manufacturing capabilities;
- successful launch of commercial sales of our drug candidates, if and when approved;
- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs, as some of our drug candidates, including our two Core Products, are not first-in-class products and will need to compete with marketed products upon potential marketing approval;
- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our drug candidates;
- successful defense against any claims brought by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and
- the continued acceptable safety profile of our drug candidates following regulatory approval.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used modalities. For example, we have built a highly differentiated portfolio of novel ADC drugs – one of the fastest-growing treatment modalities for cancers with vast market potential. Our ADC assets and other drug candidates, given their novelty and differentiated features, may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Furthermore, a substantial amount of education and training may need to be provided to patients and medical personnel, which potentially increases our sales and marketing expenses. This may have a material adverse effect on future profits generated from our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

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As of the Latest Practicable Date, except for A167 and A166 for which we had filed an NDA, respectively, all of our other drug candidates were in various phases of preclinical and clinical development. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 in the China market in the second half of 2024 or the first half of 2025. If we encounter any challenges arising from one or more of the aforementioned factors, we could experience significant delays or difficulties in obtaining approvals for and commercializing our drug candidates, which would have a material adverse effect on our business, financial condition and results of operations.

We may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The biopharmaceutical industry in which we operate is highly competitive and rapidly changing. While we focus on developing drug candidates with the potential to become novel or highly differentiated drugs, we face competition with respect to our current drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. For instance, our Core Products SKB264 and A166, upon potential marketing approval, will face competition from existing ADCs directed against the same molecular targets and approved for the same target indications.

Large multinational pharmaceutical companies, well-established biopharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of indications which our drug candidates also target. For example, in recent years, an increasing number of biotechnology companies have joined the competition in the research and development of ADCs, with large pharmaceutical companies leading the competition and small biotechnology companies making frequent breakthroughs. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on different approaches. See “Business – Our Pipeline.” Moreover, merger and acquisitions of large pharmaceutical companies in the ADC market may increase the competitiveness of such companies, which we may not be able to compete against effectively.

Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Many of our competitors have substantially greater financial, technical and other resources, such as more advanced commercial infrastructure, more drug candidates in late-stage clinical development, more seasoned research and development staff and well-established marketing and manufacturing teams than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the biopharmaceutical industry

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may result in even more resources being concentrated in our competitors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive position.

Competition may further intensify as a result of advances in the commercial applicability of technologies and availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective with a lower cost than our drug candidates, or achieve earlier patent protection, regulatory approvals, product commercialization and market penetration than we do. To compete with an approved product, we must demonstrate compelling advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or noncompetitive.

Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is capital-intensive and may demand years of effort to complete, while its outcomes are inherently uncertain and may not be favorable. For instance, despite showing vast potential in clinical trials in the 1980s for cancer treatment, ADCs have presented a major scientific challenge to researchers due to the high degree of technological sophistication required to design and produce a balanced drug. Only recently have ADCs begun to gain momentum, with a total of 12 FDA-approved ADCs to date. For details, see “Industry Overview – The Antibody-Based Market – The ADC Market.”

We may encounter unexpected difficulties while executing our clinical development plans for our drug candidates, including but not limited to the ADC assets. Failure can occur at any time or stage during the clinical development process, which would result in a material and adverse effect on our business, financial condition and results of operations. For instance:

- regulators, ethics committees, or other designated review bodies may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including negative results or a finding that participants are being exposed to unacceptable health and safety risks;
- we may not be able to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation;

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- we may encounter various manufacturing issues, including inability to reach agreements on acceptable terms with CMOs, delay in constructing our new manufacturing facilities, problems with quality control, or ensuring sufficient quantities of our drug candidates for use in a clinical trial;
- subject enrolment may be insufficient or slower than we anticipate, or subjects may drop out at a higher rate than anticipated; and
- our drug candidates may cause adverse events and undesirable side effects, among other unexpected characteristics, which could result in a suspension or termination of an ongoing trial.

Furthermore, the results of preclinical 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 indicate the success of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is also common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire research and development stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

There may be significant variability in safety or efficacy results among different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in size and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability between clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and deviate from our expectation, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. See also “– Risks Relating to Government Regulations – The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and uncertain. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our targeted markets, our business may be subject to actual or perceived harm.”

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We may not be able to identify, discover or in-license new drug candidates, or to identify additional therapeutic opportunities for our drug candidates.

Besides the continued clinical testing, potential approvals and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, discover or in-license additional drug candidates.

There can be no assurance that we will be successful in identifying new drug candidates in the future. For example, although we have developed a proprietary ADC technology platform, which we believe enables us to design, evaluate and select candidates and continue to enrich our pipeline, we cannot guarantee that we will successfully identify potential drug candidates as expected. Some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We have also pursued, and may continue to pursue, collaboration with third parties in the discovery and development of potential drug candidates, including through co-development and licensing arrangements. For details, see “Business – Our License and Collaboration Arrangements.” However, there can be no assurance that such license and collaboration will deliver the expected results.

Research programs to identify new drug candidates and to develop our drug candidates for additional indications require substantial technical, financial and human resources. We may invest efforts and resources in potential drug candidates or indication expansions that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

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 selected 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 selected indications may not yield any commercially viable products. Furthermore, 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 licensing, collaboration or royalty arrangements in cases where 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.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may experience difficulties in subject enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the subject eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of subjects to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- 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;
- our ability to obtain and maintain subject consents;
- the risk that subjects enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials may compete with our competitors' clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. Such competition will likely reduce the number and types of subjects available to us, as some patients might opt to enroll in a trial being conducted by our competitors instead of ours. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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Adverse events or undesirable side effects 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 (“AEs”) and undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our drug candidates, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. Results of trials conducted by us or by our licensing partners with respect to our licensed drug candidates could reveal a high and unacceptable severity or prevalence of certain AEs. In such an event, such trials could be suspended or terminated and the NMPA, the FDA, or other comparable regulatory authorities could order us or our licensing partners, as applicable, to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, if we, our licensing partners, or others identify undesirable side effects caused by our drug candidates after they receive regulatory approval, this may lead to potentially significant negative consequences which include, but are not limited to, the following:

- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug candidate;
- we, or our licensing partners, may have to suspend marketing of the drug candidate;
- regulatory authorities may require additional warnings on the label;
- the NMPA, the FDA or a comparable regulatory authority may require the establishment of a Risk Evaluation and Mitigation Strategy (REMS), or other similar plans, which may restrict distribution of our drugs and impose burdensome implementation requirements on us, among other risk mitigation tools;
- we, or our licensing partners, may be required to change the way the drug candidate is administered, or conduct specific post-marketing studies;
- we could be subject to litigation proceedings and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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Further, combination therapy using our drug candidates together with third-party agents may involve AEs, which in some cases could be exacerbated compared with AEs from monotherapies. Any of these events could prevent us or our licensing partners, as applicable, from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, financial condition, results of operations and prospects.

We may be unable to successfully develop or market our drug candidates or may experience significant regulatory delays, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates.

We plan to develop certain of our drug candidates, such as SKB264 and A167, for combination therapies. For example, we obtained IND approvals from the NMPA in March and April 2022 for two phase 2 clinical trials for SKB264 combination therapies – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a 1L treatment for advanced TNBC, for which we expect to complete patient enrollment in the second half of 2023 and the first half of 2024, respectively. We also received IND approvals from the NMPA and FDA in July 2022 and November 2022, respectively, for a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors, which we commenced in December 2022 in both China and the U.S. For SKB264’s phase 2 basket study as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC, we received IND approval from the NMPA in January 2023.

If the NMPA, the FDA or other comparable regulatory authorities revokes its approvals of the pharmaceutical products or medical treatments we intend to use in combination with our drug candidates, we may not be able to develop or market our drug candidates as a combination therapy as planned. In addition, if safety or efficacy issues arise with these pharmaceutical products or medical treatments that we seek to combine with our drug candidates, we may also experience significant regulatory delays, and be required to re-design or terminate the relevant clinical trials. Moreover, if manufacturing or other issues result in a supply shortage of any component in the combination therapies we are developing, we may not be able to complete clinical development of our drug candidates under our target timetable or within our current budget, or at all.

We invest substantial human and capital resources in research and development in order to develop our drug candidates and enhance our technologies, but we cannot guarantee that such efforts will lead to successful outcomes.

The global biopharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For example, we have made significant efforts to develop our core technology platforms, namely, our ADC platform, biologics platforms and small molecule platform, which allow us to continuously

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develop and manufacture a strong pipeline of drug candidates. For the years ended December 31, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million and RMB1,122.8 million, respectively. We intend to continue to strengthen our technical capabilities in the development and manufacture of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant net losses since inception. We anticipate that we will continue to incur net losses and may fail to achieve or maintain profitability in the future.

[REDACTED] in the development of biopharmaceutical products is highly speculative as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we financed our operations primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from our Series A Financing. We had not generated any revenue from the sales of commercialized products as of the Latest Practicable Date, and we continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant net losses since our inception. For the years ended December 31, 2021 and 2022, our net losses were RMB889.8 million and RMB616.1 million, respectively.

Substantially all of our net losses during the Track Record Period resulted from costs and expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials, which exceeded the revenue we recognized from out-license agreements and provision of research and development services. For the years ended December 31, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million and RMB1,122.8 million, respectively. See “Financial Information – Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income” for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

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We expect to continue to incur net losses in the foreseeable future and that these net losses may increase as we carry out certain activities, including but not limited to the following:

- continue to advance the clinical trials and preclinical studies for our product pipeline;
- seek to discover, develop or in-license additional drug candidates and further expand our product pipeline;
- seek regulatory approvals for our drug candidates to commence commercialization;
- manufacture our drug candidates for clinical trials and for commercial sale;
- develop or manufacture drug candidates under any existing or future license and collaboration arrangements, and the timing and amount of milestone and other payments that we receive from or pay to third parties. See also “– Risks Relating to Dependence on Third Parties – We have entered into license and collaboration agreements with third parties in the development of our drug candidates, and may seek additional license and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected”;
- commercialize drug candidates in our pipeline for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- attract and retain skilled personnel; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a public company following the completion of this [REDACTED].

Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our net losses have had, and will continue to have, an adverse effect on our working capital and shareholders’ equity. Our failure to become and remain profitable may affect [REDACTED] perception of the potential value of our Company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the market [REDACTED] of our H Shares. A decline in the [REDACTED] of our H Shares could cause potential [REDACTED] to lose all or part of their [REDACTED] in our business.

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We incurred net liabilities, net current liabilities and net operating cash outflows and net operating cash outflows during the Track Record Period, which may continue into the foreseeable future and expose us to liquidity risk.

As of December 31, 2021 and 2022, we had net liabilities of RMB2,643.9 million and RMB3,226.2 million, respectively. The increase was primarily due to the loss for the year of RMB616.1 million we recorded in 2022, as a result of the significant capital we invested into the research and development of our extensive drug pipeline, and building up our technology platforms, manufacturing facilities and other capabilities to complement and support our business. In addition, we recorded net current liabilities of RMB3,146.6 million and RMB3,835.0 million as of December 31, 2021 and 2022, respectively, mainly attributable to bank loans and other borrowings of RMB2,388.0 million and RMB2,890.8 million, respectively, as of the same dates, which we borrowed primarily from Kelun Pharmaceutical to fund our investments in our business. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. Primarily as a result of this debt-to-equity swap, our net current liabilities decreased to RMB947.9 million as of April 30, 2023. See “Financial Information – Material Related Party Transactions” for details.

A net liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorably or commercially reasonable to us, or at all. See also “– Risks Relating to Our Financial Position and Need for Additional Capital – We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.”

We had cash used in operating activities of RMB485.9 million and RMB270.8 million for the years ended December 31, 2021 and 2022, respectively, primarily for our research and development activities. We may experience net cash outflows from our operating activities from time to time. See also “Financial Information – Liquidity and Capital Resources – Working Capital Sufficiency.” Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect.

If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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We have a limited operating history as a standalone company, which may make it difficult to predict our future performance.

We are a clinical-stage biopharmaceutical company with a relatively short operating history as a standalone company, starting from 2016 after the completion of the Reorganization. See “History and Corporate Structure.” Our operations to date have focused on establishing our intellectual property portfolio, conducting drug discovery, preclinical studies and clinical trials of our drug candidates, forging collaboration and strategic partnerships globally, and organizing and staffing our operations. As of the Latest Practicable Date, we had not yet obtained marketing approval for or commercialized any drug candidates, nor had we generated any revenue from product sales.

We also have limited experience in commercial-scale manufacturing and the sales and marketing of approved drugs. For these reasons, particularly in a rapidly evolving biopharmaceutical industry, it may be difficult to predict our future performance. We may encounter unforeseen expenses, challenges, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business may suffer.

We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we financed our operations, including our R&D activities in relation to our preclinical studies and clinical trials, primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from our Series A Financing. As of December 31, 2021 and 2022, our borrowings from Kelun Pharmaceutical were RMB2,358.0 million and RMB2,790.8 million, respectively. As of the Latest Practicable Date, all the outstanding principal and interest of our borrowings from Kelun Pharmaceutical had been settled. See also “Financial Information – Material Related Party Transactions.”

We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. Although we are conducting this [REDACTED], we may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;

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- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- the amount and timing of any milestone and royalty payments we receive from or pay to our current or future collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the cash requirements of any future acquisitions and/or development of in-licensed pipeline drug candidates; and
- our headcount growth and the associated costs.

As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

Our ability to raise funds will also depend on the prevailing financial, economic and market conditions and factors from other aspects, such as our relationship with commercial banks, many of which are beyond our control. See also “– Risks Relating to Our Operations – Disruptions in the financial markets and economic conditions could affect our ability to raise capital.” If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities, or the commercialization of one or more of our drug candidates, which may adversely affect our business prospects.

We are subject to credit risk arising from trade and other receivables and amounts due from related parties.

As of December 31, 2021 and 2022, we had trade and other receivables of RMB78.5 million and RMB98.7 million, respectively, which primarily consist of prepayments to suppliers and service providers, and VAT recoverable. As of the same dates, we had amounts due from related parties of RMB22.7 million and RMB61.8 million, respectively, primarily representing amounts due from Kelun Group for R&D services we provide. We may be exposed to credit risk with our counterparties and may not be able to collect all of such receivables due to a variety of factors that are outside of our control. If the relationship between us and any of our counterparties is terminated or deteriorated, or if our counterparties experience financial or operational difficulties, the recoverability of our receives may be negatively affected, which may have a material and adverse effect on our business, financial condition and results of operations.

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We may face risk regarding the obsolescence for our inventories.

During the Track Record Period, our inventories primarily consisted of raw materials and low-value consumables purchased for our R&D activities and day-to-day operations. As of December 31, 2021 and 2022, our inventories amounted to RMB50.7 million and RMB52.6 million, respectively. During the Track Record Period, we have not identified material inventory items requiring impairment provision. However, we cannot assure you that our inventory management system will be effective in the future and forecasts for our inventory levels are inherently uncertain. If our forecast demand is higher than actual demand, we may face risk of inventory obsolescence or write-offs, which may increase our inventory holding costs. Furthermore, as our business expands, our inventory level may increase and our inventory obsolescence risk may also increase accordingly, which could materially and adversely affect our financial condition and results of operations.

We face exposure to fair value change of financial assets at FVPL and valuation uncertainty due to the use of unobservable inputs.

As of December 31, 2021 and 2022, and April 30, 2023, we had financial assets at FVPL of nil, nil and RMB400.0 million, respectively, which represented wealth management products we purchased. For the years ended December 31, 2021 and 2022, we recorded net realized and unrealized gain on financial assets at FVPL of RMB0.4 million and RMB0.5 million, respectively. After [REDACTED], we may continue to purchase low-risk wealth management products with a short maturity period based on our operational needs. We therefore face exposure to fair value change of financial assets measured at FVPL.

We cannot assure you that we can recognize comparable fair value gains in the future and we may on the contrary recognize fair value losses, which would affect our result of operations for future periods. In addition, the valuation of financial assets at FVPL is subject to uncertainties due to the use of unobservable inputs. Such estimated fair values involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the valuation of financial assets at FVPL has been, and will continue to be, subject to uncertainties in estimations, which may not reflect the actual fair value of these financial assets and result in fluctuations in profit or loss from year to year.

We may not be able to fulfil our obligations in respect of contract liabilities.

During the Track Record Period, our contract liabilities primarily represented amounts we received from MSD before we had reached the relevant milestones as contemplated in the relevant license and collaboration agreements. We recorded contract liabilities of RMB109.0 million and RMB164.0 million as of December 31, 2021 and 2022, respectively.

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There is no assurance that we will be able to fulfil our obligations in respect of contract liabilities due to various factors, including the failure of reaching development milestones, disrupted supply of raw materials and consumables from our suppliers, or other factors beyond our control. If we fail to fulfill such obligations, we may not be able to recognize the related revenue in a timely manner, if at all, which may adversely affect our business, financial condition and results of operations. Moreover, we may be in breach of our contractual obligations and may be subject to liability or claim of refund, as well as suffer reputational damage. In such an event, we may experience a shortage of cash and have difficulty funding our operations, which may have a material and adverse effect on our business, financial condition, and results of operations.

Share-based payments may have a material and adverse effect on our financial performance and cause shareholding dilution to our Shareholders.

We have established Employee Incentive Platforms for the benefit of our core employees, Directors and senior management as remuneration for their services provided to us and to incentivize and reward the eligible persons who have contributed to the success of our Company. For further details, see “History and Corporate Structure – Employee Incentive Platforms.” For the years ended December 31, 2021 and 2022, we incurred share-based payment expenses of RMB6.5 million and RMB19.8 million, respectively.

To further incentivize our employees, we may incur additional share-based payment expenses in the future. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a negative effect on our financial performance. Issuance of additional H Shares with respect to such share-based payments may dilute the shareholding of our Shareholders and could result in a decline in the value of our H Shares.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We have entered into license and collaboration agreements with third parties in the development of our drug candidates, and may seek additional license and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. To date, we have entered into nine out-license agreements, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. See “Business – Our License and Collaboration Arrangements” for details.

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Our revenue from license and collaboration agreements increased significantly during the Track Record Period and our results of operations have been, and may continue to be, affected by such arrangements. For the years ended December 31, 2021 and 2022, 13.8% and 97.8%, respectively, of our total revenue was derived from our license and collaboration agreements with MSD and other licensing partners. We also generated revenue from provision of research and development services to Kelun Group and other third parties, which constituted 86.2% and 2.2%, respectively, of our total revenue for the same years. License and collaboration agreements involving our drug candidates are subject to various risks, which may include the followings:

- the license and collaboration agreements may be terminated upon a short notice, or if we or our business partners fail to comply with the obligations as set out in the respective agreements. Our business partners may elect to cease collaboration due to change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors. Termination of license and collaboration arrangements may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidates;
- the milestone payments and royalties under the license agreements are conditioned upon the achievements of certain regulatory, development and commercialization targets. We cannot guarantee that we will be able to receive the aggregate amount as set out in the relevant license and collaboration agreements;
- our business partners may have significant discretion in determining the efforts and resources that they will apply under license and collaboration agreements;
- our business partners could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- our business 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;
- our business partners may own or co-own intellectual property covering our drug candidates or future drugs that arise from our license and collaboration agreements with them, in such cases we may not have exclusive right over such intellectual property; and
- disputes may arise between us and our business 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. See also “– Risks Relating to Our Intellectual Property Rights – Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others.”

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For these and other reasons, we may not achieve the outcomes and synergies expected from our license and collaboration arrangements. These license and collaboration arrangements are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. We may face operational and financial risks including increase in near- and long-term expenditures, exposure to unknown liabilities, disruption of our business and diversion of our management’s time and attention. Even if we achieve the expected benefits, we may not be able to do so within the anticipated time frame.

We face significant competition in seeking appropriate strategic partners and the negotiation process can be 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 of a stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits. See also “– Risks Relating to Our Operations – Our potential engagement in acquisitions or strategic partnerships in the future 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.”

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay 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 license and collaboration arrangements or 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, financial condition, results of operations and prospects.

As a result, we cannot be certain that, following a license and collaboration arrangement, we will achieve the revenue or net income that justifies such transaction or such other benefits that caused us to enter into the arrangement. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our drug candidates and certain of these third parties from which we have been granted licenses themselves rely on licenses from other third parties. For example, under the co-development agreement among our Company, Kelun Research Institute, Levena, Contortis, and Sorrento Therapeutics, Inc. (NYSE: SRNE) for A166, our HER2 ADC, we were granted the right to utilize Levena’s all patents (registered or pending) and other technical know-how related to its linker and payloads.

As of the Latest Practicable Date, among the patents and patent applications we licensed from Levena that cover A166, only one patent application was pending in China, and no patent had been issued in China. If this patent application is subsequently granted in its original scope, and in the unlikely event that our collaboration with Levena is terminated early, we may not be able to utilize this issued patent for A166’s development and commercialization. As a result, we may need to negotiate further commercial arrangements with Levena or any other party then holding the rights to the applicable technologies, which may affect our ability to commercialize A166 as planned, or at all, and divert management attention. For details as to the termination clause set out in the collaboration agreement with Levena, see “Business – Our License and Collaboration Arrangements – Cooperative Development Agreement with Levena for A166.”

The licenses we hold may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to develop, export or sell our drug products outside of the fields or territories as stipulated by the license and collaboration agreements or prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensing partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject to such licensed rights could be adversely affected. Our licensing partners may have relied on third-party consultants or collaborators or on funds from third parties, or on upstream licenses from third parties, such that our licensing partners are not the sole and exclusive owners of the intellectual property rights we in-license. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Such license agreements set out various procedures and timelines with respect to, among other matters, clinical development, commercialization, and financial obligations such as milestone payments and

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royalties. The terms of these agreements are complex and can be subject to multiple interpretations. The resolution of any disagreements arising from these agreements could, for example, eliminate or narrow what we believe to be the scope of our rights to the relevant intellectual properties or technologies, or increase what we believe to be our financial or other obligations under the relevant agreements. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate such agreements, in which event we might lose the ability to develop, manufacture or market certain drugs, or face claims for monetary damages or other penalties under the respective agreements. Reduction or elimination of our rights under such agreements may force us to negotiate new or restated agreements with less favorable terms, or cause disruptions to our ongoing activities carried out in reliance of such rights, including our rights to important intellectual properties and technologies.

Moreover, if any of our licensing partners encounter financial problems or changes in business focus, some or all of our rights under the license agreements may be terminated. For details, see “Business – Our License and Collaboration Arrangements.” As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We rely on third parties to monitor, support and/or conduct clinical trials and preclinical studies of our drug candidates. 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 affected.

We have relied upon and plan to continue to rely upon third-party CROs, clinical trial sites, consultants and other third parties to monitor, support and conduct preclinical studies and clinical trials of our drug candidates. As a result, we do not have full control over their activities or the quality, timing and cost of these studies. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

In particular, we, our CROs and our clinical investigators are required to comply with GCP, GLP and other regulatory regulations and guidelines enforced by the NMPA, the FDA, and comparable regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities may enforce these GCP, GLP or other regulatory requirements through periodic inspections of trial sponsors, investigators and trial sites. In addition, our clinical trials must be conducted with drug candidates or products produced under current cGMP requirements.

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Notwithstanding the remedies available to us under our agreements with our CROs, we cannot control whether or not such CROs will devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If we or any of our CROs fail to comply with the applicable GCP, GLP, cGMP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA, or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance the regulatory authorities will determine that our clinical trials comply with all the applicable requirements. Failure to comply with these regulations may lead us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Similarly, if other third parties fail to meet expected deadlines, timely transfer to us any requisite information, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a sub-standard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, the clinical trials of our drug candidates may be compromised, delayed, prolonged, suspended or terminated, or our data may be rejected by the NMPA, the FDA, or other comparable regulatory authorities. In addition, the use of these third parties may require us to disclose our proprietary information or confidential information concerning the subjects enrolled in our clinical trials from time to time, which could increase the risk that such information will be misappropriated. Though we carefully manage our relationships with our CROs and other third-party service providers, there can be no assurance that we will not encounter challenges in the future or that these challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, we may not be able to enter into arrangements with alternative CROs and other third parties in a timely manner or do so on commercially reasonable terms, if our existing relationships with these third parties terminate. Switching or adding CROs and other third parties involves additional cost and delays, which can materially affect 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, financial condition and prospects.

We depend on third parties to provide a stable and adequate supply of quality materials and products for our drug development and manufacturing needs. Any interruptions of or significant price increases in such supply could adversely affect our business.

During the Track Record Period, we relied on third parties to supply certain raw materials and products used in our research and development, and the manufacturing of drugs for clinical trials. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our drug candidates.

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Any disruption in production or the inability of our suppliers to provide adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates. Moreover, we expect our demand for such raw materials and products to increase as we expand our business scale and commercialize our drug candidates, but there is no assurance that current suppliers have the capacity to meet our demand. We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In addition, although we have implemented quality inspection on such raw materials and products before using them in the manufacturing process, we cannot assure you that we will be able to identify and rectify all quality issues.

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

We may rely on third parties to manufacture our drug products for clinical development and commercial sales. Our business could be harmed if these third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality or price levels.

During the Track Record Period, we outsourced certain manufacturing activities to reputable CMOs in China. See “Business – Manufacturing – CMOs” for details. Going forward, we intend to continue to engage third-party CMOs to manufacture our drug candidates for our research and development activities and commercial sales. Reliance on third-party CMOs exposes us to certain risks, including but not limited to the following:

- we may be unable to identify CMOs on acceptable terms or at all because the number of qualified CMOs is limited and the NMPA, the FDA or other comparable regulatory authorities must evaluate and/or approve any CMOs as part of their regulatory oversight of our drug candidates;
- our CMOs may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;
- our CMOs are subject to periodic inspections and other government regulations by the NMPA, the FDA or other comparable regulatory authorities, including to ensure strict compliance with the cGMP. We do not have full control over our CMOs’ compliance with these regulations and requirements;
- our CMOs might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;

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- our CMOs may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed;
- our CMOs 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;
- our CMOs may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- our CMOs could terminate their agreements with us;
- raw materials and products procured by certain CMOs may not be readily obtainable elsewhere; and
- natural or man-made disasters, labor disputes, unstable political environments and other events beyond our control may lead to interruption of the manufacturing process.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs, or adversely impact commercialization of our future approved drug candidates.

We may fail to effectively manage our network of distributors after our drug candidates are successfully launched. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

We may rely in part on third-party distributors to distribute our drug candidates upon their commercialization. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely and effective delivery of our products to the relevant markets. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach the distribution agreements and the policies and measures we have in place to manage their distribution. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

- breaching the distribution agreements or our policies and measures;
- failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements when selling our products; or
- violating anti-corruption, anti-bribery, competition or other laws and regulations of China or other jurisdictions.

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Any violation or alleged violation by our distributors of the distribution agreements, our policies or any applicable laws and regulations could expose us to liabilities and monetary damages, a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects.

Our relationships with certain principal investigators, KOLs and leading hospitals may affect the clinical development and future marketing of our products.

Our relationships with principal investigators, KOLs, and leading hospitals play an important role in our R&D and marketing activities. We implement a clinical demand-oriented and highly responsive R&D strategy by establishing extensive interaction channels with principal investigators, KOLs, leading hospitals to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs and improve our existing drug candidates. We are planning to develop our own commercialization team and network, with an initial focus on Class III hospitals and leading physicians across China’s extensive local markets. We are also committed to enhancing our collaborations with KOLs, top hospitals and academic institutions, in China and globally, to ensure our timely access to cutting-edge research and support our existing and future pipeline. See also “Business – Our Development Strategies” and “Business – Commercialization.”

However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs and leading hospitals, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our R&D process, may be inaccurate and lead us to develop drugs that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable drugs. If we are unable to develop new drugs or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

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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 world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our drug candidates may be adversely affected.

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology 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 technology that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of the Latest Practicable Date, we owned (i) 74 issued patents in China, (ii) 21 issued patents in the U.S., (iii) 52 issued patents in other jurisdictions, and (iv) 255 pending patent applications, including 100 in China, 14 in the U.S., 16 under the Patent Cooperation Treaty (PCT) and 125 in other jurisdictions. See “Business – Intellectual Property” for details. This process is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The patent position of biopharmaceutical companies generally involves complex legal and factual questions, and can be frequently litigated. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not be granted with approvals that effectively prevent third parties from commercializing competitive technologies and drug candidates. The patent examination process may require us or our business partners to narrow the scope of our or our business partners’ pending and future patent applications, which may then limit the scope of patent protection that could be obtained. There can be no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent. Moreover, if there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable.

Even if patents are issued on these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. We or our business partners may become involved in interference, *inter partes* review, post-grant

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review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. 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.

The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in any jurisdictions. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours. Our competitors may also be able to circumvent our patent issuance by developing similar or alternative technologies or drug candidates in a non-infringing manner.

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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (the “CNIPA”), the United States Patent and Trademark Office (the “USPTO”) and other applicable patent agencies in several stages over the lifetime of a patent. The CNIPA, the USPTO and other applicable patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application 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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If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in China 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 U.S. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and 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 product exclusively, which would have a material adverse effect on any potential sales of that product. 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 owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product 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. Similarly, the amendment to the PRC Patent Law which was promulgated in October 2020 introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five 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.

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Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed.

In addition, 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 products and technology. Besides this, 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 could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights, or prevent unfair competition by third parties, throughout the world.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions 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, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

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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. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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 own a number of trademarks in China, the U.S. and other jurisdictions. 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 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, 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.

In addition to our issued patents and pending patent applications, we rely on 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 collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers 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 or violate the terms of any such

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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.

Furthermore, many of our employees, consultants and advisors were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and advisors, including our senior management members, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors are under no non-competition obligations to their former employers at the time of hiring, and that they do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management or general management, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, 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. 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 against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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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.

Changes in intellectual property laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the scope and value of our intellectual property rights.

For example, after March 2013, under the Leahy-Smith America Invents Act (“Leahy-Smith Act”), the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published 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. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

There could be similar changes in the laws of China, such as the amendment to the PRC Patent Law which was promulgated in October 2020. See “– Risks Relating to Our Intellectual Property Rights – If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.” Such changes in laws either of China or foreign jurisdictions may impact the value of our patent rights or our other intellectual property rights, all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial conditions, results of operations and prospects.

We may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time consuming and unsuccessful.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights (including those transferred or licensed from our Controlling Shareholder or other third parties) could be challenged or invalidated. For example, although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. On the

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other hand, competitors or other third parties may infringe or misappropriate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages. In addition, if the breadth or strength of protection provided by our patents and other intellectual property rights is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of intellectual property protection could have a material adverse impact on one or more of our drug candidates and our business.

An adverse result in any litigation or defense proceedings could put one or more of our intellectual property rights at risk of being invalidated or interpreted narrowly. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If the public, securities analysts or [REDACTED] perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the [REDACTED] of our Shares. There is no assurance that our drug candidates will not be subject to the same risks.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business nor permit us to maintain our competitive advantages. The following examples are illustrative:

- others may be able to make drug candidates that are the same as or similar to our drug candidates but that are not covered by the claims of the patents that we own or may have exclusively licensed;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

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- third parties 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; and
- we may not develop additional technologies that are patentable.

RISKS RELATING TO GOVERNMENT REGULATIONS

All material aspects of the research, development, manufacturing and commercialization of biopharmaceutical products are heavily regulated. Any failure to comply with relevant laws, regulations and industry standards or any adverse actions by the regulatory 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 regulate these activities in great depth and detail. See also “– Risks Relating to Doing Business in China.” Apart from our focus on the China market, we are actively seeking opportunities to expand our global footprint and raise international brand awareness. For more details, please see “Business – Our Development Strategies.” Such jurisdictions all strictly regulate the biopharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of 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.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and capital resources. Failure to comply with the applicable regulatory requirements in the jurisdictions we operate or target to operate in the future at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to 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. Any occurrence of the foregoing could therefore materially adversely affect our reputation and our business, financial condition, results of operations and prospects.

In many countries or regions where a drug is intended to be ultimately sold, including China and the U.S., the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. For example, we may need to obtain clearance from the NMPA, the FDA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA, BLA or other similar applications to

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seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and uncertain. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our targeted markets, our business may be subject to actual or perceived harm.

The time required to obtain approvals from the NMPA, the FDA, and other comparable regulatory authorities is unpredictable and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take many years to obtain, following the commencement of preclinical studies and clinical trials. We cannot assure you that we will be able to meet regulatory 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.

We may fail to receive the regulatory approvals from the NMPA, the FDA or other comparable regulatory authorities for our drug candidates due to a number of reasons, including:

- disagreement in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- insufficient or suboptimal data collected from the clinical trials, or failure of our clinical trial results to meet the level of statistical and medical significance required for approvals;
- failure of our clinical trial process to pass GCP inspections;
- unexpected changes in regulations, testing requirements, or approval policies that render our preclinical and clinical data insufficient for approval;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities, resulting in a potential invalidation of our research data; and

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- findings of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies, such as failure to pass cGMP inspections.

The NMPA, the FDA or other comparable regulatory authorities may require more information to support approval, including additional preclinical or clinical data, which may result in delay in regulatory approval and commercialization plans or denial of regulatory approval. In the case where an approval is issued, regulatory authorities may approve fewer indications, including undesired indications, of our drug candidates than the indications we applied for, or grant approvals contingent on the performance of post-marketing clinical trials. Failure to obtain regulatory approvals in a timely manner, or at all, or failure to obtain regulatory approvals with an intended scope of indications could have a negative impact on the commercial prospects of our drug candidates, and may cause reputational damage. If any of our drug candidates fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or does not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidate despite the significant amount of resources we would have spent on its development, which could materially adversely affect our business, financial condition, results of operations and prospects.

If we are unable to obtain approval from the NMPA, the FDA and other comparable regulatory authorities for our drug candidates to be eligible for an expedited registration pathway as innovative or breakthrough therapy, the time and cost we incur to obtain regulatory approvals may increase.

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may have implemented expedited review programs for drug candidates, among others, which are innovative drug applications, or which treat a serious or life-threatening condition and provide meaningful therapeutic benefit over available therapies. The NMPA's Breakthrough Therapy Designation, for example, is intended to facilitate and expedite the development and review of an investigational drug to treat a serious disease or condition when preliminary clinical evidence indicates that the drug has demonstrated substantial improvement over current therapies. Similarly, the FDA may facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical need for the condition.

Supported by its promising proof-of-concept results, SKB264, our TROP2 ADC, was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. There can be no assurance, however, that the regulatory authorities will consider granting Breakthrough Therapy Designation or other expedited review programs for our other or future drug candidates, or that we will decide to pursue or submit any applications for accelerated approvals or any other form of expedited development, review or approvals. Similarly, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approvals or any other form of expedited

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development, review or approvals, even if we initially decide to do so. Furthermore, there can be no assurance that such a submission or application will be accepted for filing, or that any expedited development, review or approvals will be granted on a timely basis, or at all. Any failure to obtain accelerated approvals or any other form of expedited development, review or approvals for our drug candidates could result in a longer period of time prior to the commercialization of such drug candidate, an increase in the development expenses for such drug candidate and an adverse impact on our competitive position in the market.

Our future approved drug candidates will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expense. We may face penalties and other negative consequences if we fail to comply with these regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the FDA or other comparable regulatory authorities approve any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive and ongoing 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 chemistry, manufacturing, and controls ("CMC"), variations, continued compliance with current cGMPs, and GCPs 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, including, if applicable, phase 4 trials 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 other comparable regulatory authorities 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 products, it may result in, among other things:

- restrictions on the marketing or manufacturing of our drugs, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or holds on clinical trials;
- refusal by the NMPA, the FDA or other comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

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- product seizure or detention, or refusal to permit the import or export of our drug candidates; and
- injunctions or the imposition of civil, administrative or criminal penalties.

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 significantly harm our business, financial condition and prospects.

Changes in laws and regulations relating to the biopharmaceutical industry, including the ongoing healthcare reform in China, may result in additional compliance risks and costs.

In China, the U.S. and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the biopharmaceutical industry and the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. See also “– Risks Relating to Manufacturing and Commercialization of Our Drug Candidates – Our drug candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may be subject to unfavorable pricing regulations, which could make it difficult for us to sell our drugs profitably.”

In particular, the PRC government has enacted a series of new laws and regulations in recent years aimed at improving the affordability and deterring potential over-use of oncology drugs. In December 2020, for instance, the National Health Commission (“NHC”) released the Notice on the Temporary Measures Regulating the Clinical Use of Oncology Drugs (《關於印發抗腫瘤藥物臨床應用管理辦法(試行)的通知》), followed by more detailed guidance announced in its Measurement Criteria for the Reasonable Clinical Use of Oncology Drugs (2021 Version) (《抗腫瘤藥物臨床合理應用管理指標》(2021年版)) in June 2021 (“Oncology Drug Guidance”), according to which several factors will be considered to evaluate whether the oncology drugs, especially “restricted class drugs,” are under reasonable use by the medical institutions, in terms of usage rate and amount, among other criteria. The Oncology Drug Guidance sets out to designate anti-tumor drugs as “restricted class drugs” if they, among other characteristics, exhibit a poor safety profile, require sophisticated clinical administration, new to the market or prohibitively priced. If our oncology drug candidates are categorized as “restricted class drugs” after commercialization, we may face a decreased demand from the medical institutions and patients, which may adversely affect the commercialization and marketing of such drug candidates. These new laws, regulations and healthcare reform measures and others which may be adopted in the future may result in more rigorous prescription and coverage criteria, new reimbursement methods and additional downward pressure on drug prices.

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Although none of our drug candidates had been commercialized as of the Latest Practicable Date, these legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our drug candidates in the future. Moreover, because these laws and regulations are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

We face regulation and potential liability related to privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of 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 including, for example, substantial operational costs associated with changes to our data processing practices. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials 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, and results of operations or prospects.

In recent years, the PRC government has promulgated an increasing number of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), the Provisions on Protection of Personal Information of Telecommunication and Internet Users (《電信和互聯網用戶個人信息保護規定》), the Cybersecurity Review Measures (《網絡安全審查辦法》), the Data Security Law of the PRC (《中華人民共和國數據安全法》) which became effective from September 1, 2021, and the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) which became effective from November 1, 2021. Under the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), prior consent shall be obtained from the individual when personal information is being processed, unless explicitly permitted under certain circumstances. Furthermore, any data processing activities in relation to sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old are not allowed unless such activities have a specific purpose, are highly necessary and strict protective measures have been taken. Certain industry-specific laws and

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regulations may also affect the collection and transfer of personal data in China, including Administrative Regulations on Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in the confiscation of human genetic resources samples and associated data and administrative fines.

Such 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 could be held liable for the damage caused. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence.

Furthermore, our clinical trials frequently also involve professionals from third party institutions working with our staff and enrolled subjects. We cannot ensure that such persons will always comply with the applicable laws and regulations or our data privacy measures. We also cooperate with third parties including 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 a result of our failure.

Any change in the applicable laws and regulations could affect our ability to use medical data and subject us to liability for the improper use of such data. 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 cause our customers to lose trust in us and could expose us to legal claims.

If we fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties and other negative consequences 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, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our facilities can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the relevant facilities in certain jurisdictions.

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We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our facilities may affect our abilities to develop, manufacture and commercialize our pipeline products as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of research, testing, development and manufacturing of biopharmaceutical products. 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 materially and adversely our business. Other adverse effects could result from such liability, including reputational damage. 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 and adverse impact on our business, financial condition, results of operations and prospects.

Although we maintain insurance policies that cover losses arising from accidents and natural calamities in respect of our machinery, equipment, inventory and other fixed assets in our research and manufacturing facilities, as well as environmental pollution liability insurance and public liability insurance, these insurance policies may not provide adequate coverage against potential liabilities resulting from the use of or exposure to hazardous materials. Furthermore, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor 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 administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational damage and diminished profits and future earnings.

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the NMPA's approval for any of our drug candidates and begin commercializing our drugs in China in the future, our operations may become subject to various PRC fraud and abuse laws, including the

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PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), PRC Criminal Law (《中華人民共和國刑法》); doctor payment transparency laws and regulations which primarily include the Affordable Care Act (《平價醫療法案》) and the Physician Payments Sunshine Act (《醫師酬勞陽光法案》). These laws may impact, among others, our proposed sales, marketing and education programs.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focusing 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 are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or 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 damage, 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 material adverse effect on our business and results of operations.

Furthermore, 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 other improper advantages. In addition, although currently our business operations are primarily in China, we are subject to the Foreign Corrupt Practices Act (FCPA) of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. 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. See also “– Risks Relating to Our Operations – We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties.”

As we expand our operations globally, we may also become subject to similar laws and regulations from other jurisdictions. There are ambiguities as to what is required to comply with any of these laws and regulations, and if we fail to comply with such requirements, we could be subject to penalties and other negative consequences. If any of the physicians or other third parties with whom we do business are found to be not in compliance with the applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

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RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

The future commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients and others in the medical community.

Even if our drug candidates receive the requisite regulatory approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payers and other relevant parties in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs and we may not become profitable. The degree of market acceptance of our drug candidates will depend on a number of factors, including but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians' and patients' perception of our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the NMPA, the FDA or other applicable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, the FDA or other applicable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competing 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 and reimbursement by government authorities;
- 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; and
- the effectiveness of our sales and marketing efforts.

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Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

We have limited experience in commercializing innovative drugs. If we fail to establish, expand and optimize an effective sales and distribution network for our drugs, our business could be adversely affected.

Our operations to date have been largely focused on developing our drug candidates, primarily undertaking preclinical studies and conducting clinical trials. Although members of our management have years of experience relating to marketing and commercialization, we have not yet demonstrated an ability to launch and commercialize any of our drug candidates. We only recently started the process of building a commercial team and a sales force for our drug candidates. As a result, 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 launching and marketing drug candidates.

We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements for the sales and marketing of our drug candidates. 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 also depend upon the efforts of such third parties. We could 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 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 further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Our drug candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may be subject to unfavorable pricing regulations, which could make it difficult for us to sell our drugs profitably.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. We intend to seek approval to market our drug candidates in China, the U.S. and in other jurisdictions. In China, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after

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obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In China, the Ministry of Human Resources and Social Security of China, together with other government authorities, review the inclusion or removal of drugs from the China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List (the “NRDL”), regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs.

There can be no assurance that any of our future approved drug candidates will be included in the NRDL. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Patients may choose other drugs with similar efficiency but lower price which have been included in the NRDL. Additionally, even if the Ministry of Human Resources and Social Security of China or any of its local counterparts were to accept our application for the inclusion of products in the NRDL, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs.

We cannot be sure that reimbursement will be available for any approved drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

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There may also be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates 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. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Our inability to promptly obtain reimbursement coverage at intended payment rates for our drug candidates and any new drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial conditions.

The size of the potential market for our current or future drug candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our current or future drug candidates may be smaller than our estimates.

Our projections of the number of patients who have the potential to benefit from treatment with our drug candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our drug candidates may be smaller than our estimates.

Furthermore, there is no guarantee that any of our drug candidates, even if approved, would be approved for the line of therapy we are aiming for. For example, cancer therapies may be characterized as first line, second line or later line therapy depending on options for treatment and prior treatments received. For indications with well-established standard of care therapies, the NMPA, the FDA and other comparable regulatory authorities may approve new therapies initially only for later lines of therapy. While we may seek approval for our drug candidates as an early-line therapy for certain indications, there is no guarantee that they will be approved as such. As a result, even if we obtain market approval for our drug candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

The manufacturing of biopharmaceutical products is a complex process which requires significant expertise and capital investment, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.

As of the Latest Practicable Date, we had not commercialized any drug candidates and our drug manufacturing activities are primarily to facilitate our preclinical studies and clinical trials. As a result, we have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process requiring significant expertise and capital investment, in part due to strict regulatory requirements.

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Issues may arise during the manufacturing process for reasons including: (i) equipment malfunction, (ii) failure to follow specific protocols and procedures, (iii) problems with raw materials, (iv) delays in the construction of new manufacturing facilities or expansion of any future manufacturing facilities, (v) changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, (vi) changes in the type of products produced, (vii) advances in manufacturing techniques, (viii) physical limitations that could inhibit continuous supply, and (ix) the occurrence of natural disasters.

If problems arise during the production process of certain future products, a batch or several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems are not discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

We face additional manufacturing risks in relation to the CMOs we engage from time to time. See “– Risks Relating to Dependence on Third Parties – We may rely on third parties to manufacture our drug products for clinical development and commercial sales. Our business could be harmed if these third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality or price levels.” We cannot assure you that issues relating to the manufacturing of our drug candidates will not occur in the future, either relating to our own manufacturing facilities or the third-party CMOs we engage.

Failure to obtain and maintain regulatory approvals for our manufacturing facilities, delays in the construction of our new manufacturing facilities, and any disruption or suspension of manufacturing activities may affect our business and results of operations.

As of the Latest Practicable Date, our manufacturing activities were primarily limited to supporting our drug development process. Anticipating future commercialization, we are building up our own cGMP-compliant pilot-scale and commercial-scale manufacturing capabilities to ensure delivery of high-quality drug products. We also engaged, and will continue to engage, industry-recognized CMOs to supplement our in-house capacity so as to enhance efficiency and reduce operational and regulatory compliance costs. For more details, see “Business – Manufacturing.” If we fail to obtain and maintain regulatory approvals for our manufacturing facilities, or encounter delays in the construction or the approval of our new manufacturing facilities, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could also require us to raise additional funds from other sources.

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 cGMP regulations. Our manufacturing facilities are designed in compliance with the NMPA and FDA’s regulatory requirements and cGMP standards in China, the U.S. and Europe. We cannot guarantee, however, that we will be able to adequately follow and document our adherence to such cGMP

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regulations or other regulatory requirements. Remediating deficiencies, if any, can be laborious, time consuming and costly. Failure to obtain and maintain such regulatory approvals may materially affect our R&D activities, and seriously delay the clinical trials and commercialization of our drug candidates.

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, the FDA or other comparable regulatory authority standards or specifications, maintain consistent and acceptable production costs, experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. 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 products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities. We may also be subject to sanctions for failure to comply with applicable regulations, including fines, injunctions, penalties, suspension of clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, suspension or withdrawal of approvals, supply disruptions, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which may harm our business.

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

The quality of our products, including drug candidates manufactured by us for research and development purposes, will depend 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. We operate a comprehensive quality control system which extends across all key stages of the R&D, manufacturing and commercialization processes. This system is established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. See “Business – Quality Control.” 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 or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, jeopardize any cGMP 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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Counterfeit biopharmaceutical products and the illegal and/or parallel import of competing drugs may reduce demand for our drug candidates, which could have a negative impact on our reputation and business.

The illegal import of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we plan to commercialize our products. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our 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.

Furthermore, certain products distributed or sold in the biopharmaceutical market may be manufactured without proper licenses or approvals, or be 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. 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 drug candidates. In addition, theft of inventory at warehouses, plants or while in-transit, which is not properly stored and which is sold through unauthorized channels. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators’ brand name(s).

RISKS RELATING TO OUR OPERATIONS

Our future success depends in part on our ability to retain our senior management, scientific employees and other qualified personnel.

We are highly dependent on the expertise and insights of our senior management team. Recruiting and retaining qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel in the future will also be critical to our success. The loss of the services of any of these persons could impede the achievement of our research, development and

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commercialization objectives. Moreover, even though our key personnel is subject to non-compete obligations for a time period, losing our senior management may increase our competitive pressure, as they may join our competitors or start competing businesses. Furthermore, replacing executive officers, scientific employees, and other qualified personnel 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 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.

We may encounter difficulties in managing our growth and expanding our operations successfully.

Our future financial performance and our ability to commercialize our drug candidates will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. For details, see “Business – Our Development Strategies.” As we continue to implement our development strategies, we intend to expand our operations and add a significant number of managerial, R&D, manufacturing, sales and marketing, and other personnel. Our recent growth and any future growth will also impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- 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;
- improving our operational, financial and management controls, reporting systems and procedures in line with our growth.

If we are not able to effectively manage our growth and further expand our organization, we may not be able to successfully develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

RISK FACTORS

Our potential engagement in acquisitions or strategic partnerships in the future 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.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network, among others.

Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including but not limited to:

- substantial time and expenses incurred during negotiation, which do not guarantee the successful consummation of an acquisition or strategic partnership;
- impact on our financial results, such as occurrence of goodwill impairment charges and amortization expenses for intangible assets;
- increased operating expenses, including research and development expenses due to an increased number of drug candidates, administrative expenses as well as selling and distribution expenses, which result in an increased cash requirements;
- the assumption of additional indebtedness or contingents;
- the issuance of our equity securities resulting in dilution to our Shareholders;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key 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 products and drug candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and/or
- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition, which may subject us to penalties, lawsuits or other liabilities.

RISK FACTORS

Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our reputation, business, financial condition and results of operations. 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 may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and intellectual property rights. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to actions taken by our counterparties, such as our suppliers, CROs and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

Our reputation is important to our success. Negative publicity with respect to us, our Controlling Shareholder, management, employees, business partners, affiliates, or our industry, may materially and adversely affect our reputation, business, results of operations and prospect.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as CMOs, CSOs and KOLs, to advance our clinical development programs, expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

Any disputes, legal proceedings, regulatory inquiries, investigations or other actions involving us, our Controlling Shareholder, management, employees, business partners and affiliates, or any perceived unethical, fraudulent, or inappropriate conduct by any of the above, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such disputes, legal proceedings, regulatory inquiries, investigations or other actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

RISK FACTORS

We may be exposed to the risks of conducting business globally.

Overseas markets are an important component of our growth strategy. We plan to explore market opportunities overseas, where we believe there is substantial demand for our drug candidates, and we intend to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our drug candidates. We will also continue seeking licensing and co-development opportunities with global multinational companies, and expand our global clinical programs. For more details, see “Business – Our Development Strategies.”

However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including but not limited to:

- efforts to enter into license and collaboration arrangements with third parties may increase our expenses or divert our management’s attention from the development of drug candidates;
- political and economic instability as well as geopolitical tensions, including the threat of war or terrorist attacks (notably the Russia-Ukraine conflicts and the reaction of the international community, the consequences of which on the financial markets and the global business climate remain uncertain);
- differing regulatory requirements for drug approvals and marketing internationally;
- potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, and delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions;
- significant adverse changes in currency exchange rates;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad; and
- business interruptions resulting from geo-political actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue and profits from international markets.

RISK FACTORS

We benefit from certain preferential tax treatments and government grants, the expiration of or changes to which could adversely affect our profitability.

We currently benefit from certain preferential tax treatments. According to the EIT Law and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. We obtained our certificate of High and New Technology Enterprise on December 3, 2020 and is entitled to preferential income tax of 15% for the years from 2020 to 2022. 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. See Note 7 to the Accountants’ Report in Appendix I to this document for details.

Moreover, we recorded government grants of RMB16.7 million and RMB20.3 million for the years ended December 31, 2021 and 2022, respectively. These government grants primarily represent government subsidies from state and local government authorities for the purpose of compensating us for the expenses in relation to our R&D activities and construction of our manufacturing facilities. These government grants are provided to us at the discretion of the relevant government authorities, who could determine at any time to eliminate or reduce these financial incentives, and may therefore vary from period to period going forward. For more details, please see “Financial Information – Description of Selected Components of the Consolidated Statements of Profit or Loss And Other Comprehensive Income – Other Net Income/(Expense).”

Since our receipt of the government grants and eligibility for the preferential income tax treatment are subject to the government’s discretion and approval process, our net income in a particular period may be higher or lower relative to other periods partly due to the potential changes in the government grants we actually receive or preferential income tax treatment we enjoy, in addition to any business or operational factors that we may otherwise experience. There is no assurance that we will continue to receive such government grants at a similar level or at all, or be eligible to enjoy the preferential income tax treatment in the future. The discontinuation of preferential tax treatments, government grants and other financial incentives currently available to us could have an adverse effect on our financial condition, results of operations, cash flows and prospects.

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

Our operations depend in part on the skills and know-how of our employees. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further increase in labor cost, which may adversely affect our operations and financial condition. In addition, share options and other share-based incentives granted under our existing or future share-based incentive arrangements and scheme could adversely affect our costs and our results of operations. See also “– Risks Relating to Our Financial Position and Need for Additional Capital – Share-based payments may have a material and adverse effect on our financial performance and cause shareholding dilution to our Shareholders.”

RISK FACTORS

We may be subject to additional social insurance fund and housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.

Pursuant to the Chinese laws and regulations, we are required to participate in the employee social welfare plan administered by local governments. Such plan consists of pension insurance, medical insurance, work-related injury insurance, maternity insurance, unemployment insurance and housing provident fund. The amount we are required to contribute for each of our employees under such plan should be calculated based on the actual income of our employees, together with the minimum and maximum level as from time to time prescribed by national laws and regulations and local authorities. Any failure to make timely and adequate social welfare contribution for its employees may trigger an order of correction from competent authority requiring the employer to make up the full amount of such overdue social welfare contribution within a specified period of time, and the competent authority may further impose fines or penalties.

During the Track Record Period, we did not pay social insurance and housing provident fund in full for our employees. Also, we engaged third-party human resources agencies to pay on our behalf social insurance premium and housing provident funds for some of our employees during the Track Record Period. As a result, we may be required by competent authorities to pay the outstanding amount, and may be subject to late payment penalties or enforcement application made to the court. As of the Latest Practicable Date, no competent government authorities imposed administrative action, fine or penalty to us with respect to this non-compliance incident or required us to settle the outstanding amount of social insurance payments and housing provident fund contributions. We cannot guarantee you that the competent government authorities will not require us to settle the outstanding amount within the specified time limit or impose late payment penalties on us. Such actions may have a material and adverse impact on our financial position and results of operation.

Changes in U.S. and international trade policies, particularly with regard to China, may cause disruptions to our clinical development, drug manufacturing processes and other aspects of our business and operations.

The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. It remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policy related to international commerce, or other trade matters. It is unknown whether new tariffs will be imposed, or whether new laws and regulations will be enacted, or the effect that any such actions would have on us or our industry. While we have not commenced commercial sales of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and disrupt our drug development and the manufacturing of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for and competitiveness of our drugs, or prevent us from selling our drugs in certain countries. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

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

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of natural disasters, such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness, including the COVID-19 pandemic, or other adverse public health developments in China or elsewhere could materially disrupt our business and operations. For example, the extent to which COVID-19 affects our results of operations going forward will depend on the future developments of the pandemic. These uncertain and unpredictable factors include, but are not limited to, adverse effects of the pandemic on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening other risks described in this document, including those relating to our ability to initiate or continue clinical trials for our drug candidates. Moreover, since there has been a significant increase in demand for electricity supply in the PRC in August 2022, certain provinces have implemented power rationing measures to conserve fuel stocks and reduce energy intensity, including Sichuan province. As of the Latest Practicable Date, our operations had not been materially affected and our facilities had not experienced any power outage as a result of the recent power rationing measures. However, we cannot assure you that we would not experience significant power shortage or outages under similar circumstances in the future.

Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events 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 condition and results of operations.

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 as well as based on our assessment of our operational needs and industry practice. For more details, please see “Business – Insurance.” Although we maintain insurance coverage for adverse events in our clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

RISK FACTORS

In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Although we believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in the PRC, our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. 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.

We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties.

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 and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct by our employees or third parties. 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, results of operations and reputation.

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

Despite the implementation of security measures, our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

RISK FACTORS

Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them.

We have leased certain properties in China as our offices, manufacturing facilities and storage spaces. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we failed to register all of the lease agreements as tenant, which were primarily used as our offices, manufacturing facilities and storage spaces. Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. In addition, as our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. 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.

Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may materially differ from actual results.

The property valuation report prepared by Cushman & Wakefield Limited, an independent property valuer, set out in the Property Valuation Report set out as Appendix VI to this document with respect to the appraised values of our properties is based on various assumptions, which are subjective and uncertain in nature. The assumptions that Cushman & Wakefield Limited used in the property valuation report include that the seller sells the property interest in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the value of the property interest. Certain of the assumptions used by Cushman & Wakefield Limited in reaching the appraised value of our properties may be inaccurate or unreasonable. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the appraised value of our properties may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value. You should not place undue reliance on such values attributable to these properties as appraised by Cushman & Wakefield Limited.

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Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

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.

In addition, concerns over the recent Russian-Ukraine conflicts, unrest and terrorist threats in the Middle East and other territories, among others, add uncertainties to the financial markets worldwide. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term. See also “– Risks Relating to Our Operations – We may be exposed to the risks of conducting business globally.”

RISKS RELATING TO DOING BUSINESS IN CHINA

Changes in China’s economic, political, social conditions as well as government policies could adversely affect our business, financial condition, results of operations and prospects.

Due to our extensive operations in China, our business, financial condition, results of operations and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While China’s economy has experienced significant growth over the past decades, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development, such as allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, and providing preferential treatment to particular industries or companies. In addition, the PRC government continues to play a significant role in regulating industry development by imposing relevant industrial policies. Some of these measures may benefit the overall China’s economy or our industry, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, the PRC government implemented certain measures, including interest rate adjustment, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

RISK FACTORS

The legal protections available to you under the PRC legal system may be limited. It may be difficult to effect service of legal process and enforce judgments against us and our management.

A majority of our directors and our senior management personnel reside within the PRC, and a majority of their assets are located within the PRC. As a result, it may not be possible to effect service of process within certain jurisdictions outside the PRC upon us or most of our directors and senior management. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in China or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by Courts of the Mainland and the Hong Kong Special Administration 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》) (the “Arrangement”). Under 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 pursuant to 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. It is not possible to enforce a judgment rendered by a Hong Kong court in China if the parties in dispute have not agreed to enter into a choice of court agreement in writing. In addition, the Arrangement has expressly provided for “enforceable final judgment”, “specific legal relationship” and “written form.”

On January 18, 2019, the Supreme People’s Court and the government of the 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 (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “New Arrangement”), which seeks to establish a mechanism with further clarification on and certainty for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Mainland China and Hong Kong. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in Hong Kong. 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 Mainland China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

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Under the New Arrangement, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the New Arrangement. Although the New Arrangement has been signed, the outcome and effectiveness of any action brought under the New Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a PRC court.

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

A large portion of our operations are conducted in China, and are governed by 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 precedential value.

In the late 1970s, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. In particular, because these laws, rules and regulations are relatively new and may give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and binding interpretation, the enforcement of these laws, rules and regulations involve uncertainties.

We may be restricted from transferring our scientific data abroad.

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》) (the “Scientific Data Measures”), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term “state secret” is not clearly defined, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations 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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More stringent restrictions on the remittance of Renminbi into and out of the PRC and governmental control over currency conversion may limit our ability to pay dividends and other obligations, and affect the value of your [REDACTED].

The Renminbi is not currently a freely convertible currency, as 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 and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our H Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends 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 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.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

Certain of our cash and cash equivalents and amounts due to related parties are denominated in foreign currencies, and are exposed to foreign currency risk. We recorded net foreign exchange gains of RMB16.9 million for the year ended December 31, 2021, and net foreign exchange losses of RMB31.9 million for the year ended December 31, 2022. The exchange rate of the Renminbi against the U.S. dollar and other foreign currencies fluctuates and is affected by, among other things, the policies of the PRC government and changes in China’s and international political and economic conditions. It is difficult to predict how market forces or government policies may impact the exchange rate between the Renminbi and the Hong Kong dollar, the U.S. dollar or other currencies in the future.

There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of Renminbi against the Hong Kong dollar, the U.S. dollar or other foreign currencies.

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The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the Hong Kong dollar, the U.S. dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our H Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

We are a PRC tax resident and we are subject to PRC tax on our global income, and the dividends payable to [REDACTED] and gains on the sale of our H Shares by our [REDACTED] are subject to PRC tax.

As a PRC-incorporated company, under applicable PRC tax laws, we are subject to a tax of up to 25% on our global income. Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the sale or other disposition of our H Shares.

Non-PRC individuals are generally subject to PRC individual income tax under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) with respect to PRC source income or gains at a rate of 20%. We are required to withhold related tax from dividend payments paid to non-PRC resident individuals, unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. Pursuant to applicable regulations, PRC companies issuing shares in Hong Kong may generally, when distributing dividends, withhold individual income tax at the rate of 10%. However, withholding tax on distributions paid by us to non-PRC individuals may be imposed at other rates pursuant to applicable tax treaties (and up to 20% if no tax treaty is applicable) if the identity of the individual holder of H shares and the tax rate applicable thereto are known to us. There is uncertainty as to whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax.

Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC EIT at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides. 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 [REDACTED] Nominees and payments through [REDACTED]). 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

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treaty rate, payment of any such refund will be subject to the PRC tax authorities’ verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H Shares through the sale or transfer by other means of H Shares.

There remains significant uncertainty as to the interpretation and application of the relevant PRC tax laws by the PRC tax authorities, including whether and how individual income tax or EIT Law on gains derived by holders of our H Shares from their disposition of our H Shares may be collected. If any such tax is collected, the value of our H Shares may be materially and adversely affected.

The biopharmaceutical industry in China is highly regulated. Future changes in laws, regulations or enforcement policies in China could adversely affect our business.

Our operations are mainly conducted in the PRC. The biopharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the research and development, trials, approval, registration, manufacturing, packaging, licensing and marketing of new drugs and various other aspects of the operation of biopharmaceutical companies. Any violation of the relevant laws, rules and regulations may subject us to disputes, administrative sanctions, criminal sanctions and other legal proceedings. See “Regulatory Overview.” In recent years, the regulatory framework in China regarding the biopharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in, or prevent the successful development or commercialization of, our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in the country. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our H Shares. An active [REDACTED] for our H Shares may not develop and the [REDACTED] and [REDACTED] of our H Shares maybe volatile.

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

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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, results of operations and the [REDACTED] 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 reasons specific to our business, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments and healthcare policies directly affecting us, fluctuations in our cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel or actions taken by competitors, among others. Moreover, shares of other biopharmaceutical companies listed on the Stock Exchange have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in [REDACTED] not directly related to our performance.

Since there will be a gap of several days between [REDACTED] and [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares when [REDACTED] begins could be lower than the [REDACTED].

The initial [REDACTED] to the [REDACTED] of our H Shares sold in the [REDACTED] 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 five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to [REDACTED] or otherwise [REDACTED] the Shares during that period. Accordingly, holders 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 sale and the time trading begins.

Our Controlling Shareholder have substantial influence over our Company and its interests may not be aligned with the interests of our other Shareholders.

Our Controlling Shareholder, Kelun Pharmaceutical, has substantial influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of directors and other significant corporate actions. Immediately after completion of the [REDACTED], assuming the [REDACTED] is not exercised, our Controlling Shareholder will hold (including direct and indirect shareholdings) approximately [REDACTED]% of the issued share capital in our Company. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a [REDACTED] of our Company and might reduce the [REDACTED] of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Controlling Shareholder may differ from the interests of our other Shareholders. We cannot assure you that our Controlling Shareholder will not exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

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Future sales or perceived sales or conversion of significant amounts of our H Shares in the public market 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 of significant amounts of our H Shares or conversion of the Unlisted Shares, if any, by specific Shareholders subject to certain regulatory requirements, after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our H Shares. 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, or conversion of existing Unlisted Shares, if any, may occur could significantly decrease the prevailing [REDACTED] of our H Shares and our ability to raise equity capital in the future.

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or equity securities in the future.

The [REDACTED] of the H Shares is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, [REDACTED] of the H Shares in the [REDACTED] will experience an immediate dilution. In order to expand our business, we may consider [REDACTED] and [REDACTED] additional Shares in the future. [REDACTED] of the H Shares may experience dilution if we [REDACTED] additional Shares in the future at a [REDACTED] which is lower than the net tangible asset value per Share at that time. Furthermore, we may [REDACTED] Shares through the employee incentive platforms, which would further dilute Shareholders’ interests in our Company.

Payment of dividends is subject to restrictions under the PRC law and there is no assurance whether and when we will pay dividends.

No dividend has been paid or declared by our Company during the Track Record Period. Under the applicable PRC laws, the payment of dividends may be subject to certain limitations. The calculation of our profit under applicable accounting standards differs in certain respects from the calculation under IFRS. As a result, we may not be able to pay a dividend in a given year even if we were profitable as determined under IFRS. Our Board may declare dividends in the future after taking into account our results of operations, financial condition, cash requirements and availability and other factors as it may deem relevant at such time. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the PRC laws and regulations and requires approval at our shareholders’ meeting. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution.

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

Our management may spend the [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our Shareholders. We plan to use a significant portion of the [REDACTED] from the [REDACTED] for the following purposes:

- the research, development and commercialization of our Core Products, namely, SKB264 and A166;
- the research, development and commercialization of our other key products;
- the continued development of our technology platforms for ADCs, biologics and small molecules, and advance our other pipeline assets, and explore and develop new drug candidates;
- the expansion of our manufacturing facilities and quality control system to support the anticipated commercialization of our late-stage assets; and
- working capital and other general corporate purposes.

For more details, please see “Future Plans and [REDACTED].”

However, our management will have discretion as to the actual application of our [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the [REDACTED] from the [REDACTED].

Certain facts, forecasts and statistics in this document relating to the biopharmaceutical industry are derived from a third-party report or publicly available sources and may not be fully reliable.

Certain statistics, information and data contained in this document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications or other third-party reports. In particular, we have extracted and disclosed in this document certain statistics, information and data from publications and other publicly available sources relating to the drugs and drug candidates of third parties and scientific research, theories and mechanisms. We have taken reasonable care in the reproduction or extraction of the official government publications and other third-party reports for the purpose of disclosure in this document. However, we cannot guarantee the quality or reliability of such source materials. They have not been prepared or independently verified by us, the [REDACTED] or any of their respective affiliates or advisers and, therefore, we make no representation as to the accuracy of such statistics, information and data, which may not be consistent with other information compiled within or outside the PRC. Due to possibly flawed or ineffective collection methods and analysis or discrepancies between published information and market practice, such statistics, information and data in this document may be inaccurate

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or may not be comparable to statistics, information and data produced with respect to other economies. Further, there is no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as the case may be in other jurisdictions. In all cases, [REDACTED] should give consideration as to how much weight or importance they should attach to or place on such facts.

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].

Prior to the publication of this document, there has been coverage in the media regarding us and the [REDACTED], which contained 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 any responsibility for the accuracy or completeness of such media coverage or forward-looking statements. We make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media. We disclaim any information in the media to the extent that such information is inconsistent or conflicts with the information contained in this document. Accordingly, prospective [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND
EXEMPTION FROM STRICT 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 certificates of exemption from strict compliance with the relevant provisions of the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

MANAGEMENT PRESENCE IN HONG KONG

According to Rules 8.12 and 19A.15 of the Listing Rules, our Company must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Since all our business operations are not principally located, managed or conducted in Hong Kong, our Company does not, and, for the foreseeable future, will not, have two executive Directors who are ordinarily resident in Hong Kong for the purpose of satisfying the requirements under Rules 8.12 and 19A.15 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 8.12 and 19A.15 of the Listing Rules. We will ensure that there is a regular and effective communication between the Stock Exchange and us by way of the following arrangements:

- (a) both of our Company’s authorized representatives, Dr. GE Junyou (葛均友) (“**Dr. Ge**”), our Executive Director and general manager, and Ms. FUNG Wai Sum (馮慧森) (“**Ms. Fung**”), our joint company secretary, will act as our Company’s principal channels of communication with the Stock Exchange. Accordingly, the authorized representatives of our Company will be able to meet with the relevant members of the Stock Exchange on reasonable notice and will be readily contactable by telephone, facsimile and email;
- (b) each of the authorized representatives of our Company has means of contacting all Directors (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange proposes to contact a Director with respect to any matter;
- (c) each Director has provided his or her mobile phone number, office phone number, fax number (if any) and e-mail address to the authorized representatives of our Company and the Stock Exchange, and in the event that any Director expects to travel or otherwise be out of the office, he or she will provide the phone number of the place of his or her accommodation to the authorized representatives;
- (d) each of our Directors not ordinarily residing in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and will be able to meet with the relevant members of the Stock Exchange within a reasonable period of time;

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- (e) we have appointed First Shanghai Capital Limited as our compliance adviser (the “**Compliance Adviser**”), in compliance with Rule 3A.19 of the Listing Rules, who will also act as an additional channel of communication with the Stock Exchange from the [REDACTED] to the date when our Company complies with Rule 13.46 of the Listing Rules in respect of its financial results for the first full financial year immediately following the [REDACTED]. Pursuant to Rule 19A.05(2) of the Listing Rules, we shall ensure that the Compliance Adviser will have access at all times to our authorized representatives, our Directors and other officers. We shall also ensure that our authorized representatives, Directors and other officers will provide promptly such information and assistance as the Compliance Adviser may need or may reasonably require in connection with the performance of the Compliance Adviser’s duties as set forth in Chapter 3A and Rule 19A.06 of the Listing Rules. We shall ensure that there are adequate and efficient means of communication among our Company, our authorized representatives, our Directors, and other officers and the Compliance Adviser, and will keep the Compliance Adviser fully informed of all communications and dealings between us and the Stock Exchange;
- (f) any meeting between the Stock Exchange and our Directors will be arranged through the authorized representatives or the Compliance Adviser or directly with our Directors within a reasonable time frame. We will inform the Stock Exchange promptly in respect of any changes in our authorized representatives and/or our Compliance Adviser; and
- (g) we will also retain legal advisers to advise on on-going compliance requirements as well as other issues arising under the Listing Rules and other applicable laws and regulations of Hong Kong after the [REDACTED].

JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary must be an individual who, by virtue of his academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. The Stock Exchange considers the following academic or professional qualifications to be acceptable: (i) a member of The Hong Kong Chartered Governance Institute; (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 that in assessing “relevant experience”, the Stock Exchange will consider the individual’s: (i) length of employment with the issuer and other listed companies and the roles he/she played, (ii) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, Companies Ordinance, Companies (Winding Up and Miscellaneous Provisions)

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Ordinance and the Takeovers Code, (iii) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than fifteen hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules, and (iv) professional qualifications in other jurisdictions.

Our Company considers that while it is important for the company secretary to be familiar with the relevant securities regulation in Hong Kong, he/she also needs to have experience relevant to our Company’s operations, nexus to the Board and close working relationship with the management of our 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 our Company to appoint a person who has been a member of the senior management for a period of time and is familiar with our Company’s business and affairs as a company secretary.

We have appointed Mr. ZHOU Zejian (周澤劍) (“**Mr. Zhou**”) as one of our joint company secretaries. Mr. Zhou is our chief financial officer. His biographical information is set out in “Directors, Supervisors and Senior Management” section. Since Mr. Zhou does not possess a qualification stipulated in Rule 3.28 of the Listing Rules, he is not able to solely fulfill the requirements as a company secretary of a [REDACTED] issuer stipulated under Rules 3.28 and 8.17 of the Listing Rules. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules in relation to the appointment of Mr. Zhou as our joint company secretary. In order to provide support to Mr. Zhou, we have appointed Ms. FUNG Wai Sum (馮慧森) (“**Ms. Fung**”), a Chartered Secretary, a Chartered Governance Professional and an Associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom, who meets the requirements under Rules 3.28 and 8.17 of the Listing Rules, as a joint company secretary to provide assistance to Mr. Zhou, for a three-year period from the [REDACTED] so as to enable him to acquire the relevant experience (as required under Note 2 to Rule 3.28 of the Listing Rules) duly discharge his duties.

Pursuant to the Guidance Letter HKEX-GL108-20, such waiver [has been granted] on the conditions that:

- (a) Ms. Fung is appointed as a joint company secretary to assist Mr. Zhou in discharging his functions as a company secretary and in gaining the relevant experience under Rule 3.28 of the Listing Rules;
- (b) this waiver will be revoked immediately if and when Ms. Fung ceases to provide such assistance during the three-year period, and we undertake to re-apply to the Stock Exchange for a waiver in the event that Ms. Fung ceases to meet the requirements under Rule 3.28 of the Listing Rules or otherwise ceases to serve as a joint company secretary of the Company;

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

- (c) our Company will further ensure that Mr. Zhou has access to the relevant training and support to enable him to familiarize himself with the Listing Rules and the duties required of a company secretary of an issuer [REDACTED] on the Stock Exchange. The Company’s Hong Kong legal advisors have provided training to Mr. Zhou on the principal requirements of the Listing Rules and the Hong Kong laws and regulations applicable to the Company after its [REDACTED]. In addition, Mr. Zhou will endeavor to familiarize himself with the Listing Rules, including any updates thereto, during the three-year period from the [REDACTED];
- (d) Mr. Zhou has confirmed that he will attend no less than 15 hours of training courses on the Listing Rules, corporate governance, information disclosure, investor relations as well as the functions and duties of a company secretary of a Hong Kong [REDACTED] issuer during each financial year as required under Rule 3.29 of the Listing Rules; and
- (e) the waiver can be revoked if there are material breaches of the Listing Rules by our Company.

We expect that Mr. Zhou will acquire the qualifications or relevant experience required under Rule 3.28 of the Listing Rules prior to the end of the three-year period after the [REDACTED]. We will liaise with the Stock Exchange before the end of the three-year period to enable it to assess whether Mr. Zhou, having had the benefit of Ms. Fung’s assistance for three years, will have acquired relevant experience within the meaning of Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

See the section headed “Directors, Supervisors and Senior Management” in this document further information regarding the qualifications of Mr. Zhou and Ms. Fung.

EXEMPTION 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

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

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

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

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

According to section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from strict 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 strict compliance with any or all of such requirements would be irrelevant or unduly burdensome, or is otherwise unnecessary or inappropriate.

According to Rule 4.04(1) of the Listing Rules, the Accountants’ Report contained in this document must include, inter alia, the results of our Company in respect of each of the three financial years immediately preceding the issue of this document or such shorter period as may be acceptable to the Stock Exchange.

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

Accordingly, we applied to the SFC for a certificate of exemption from strict compliance with the requirements under 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, and a certificate of exemption [has been granted] by the SFC under section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the conditions that (i) the particulars of the exemption are set forth in this document, and (ii) this document must be issued on or before [REDACTED] on the following grounds:

- (a) our Company is an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;
- (b) the Accountants’ Report for the two years ended December 31, 2022 has been disclosed in the document of the Company and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;

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

- (c) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 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;
- (d) furthermore, as Chapter 18A of the Listing Rules provides track record period of two years for biotech companies in terms of financial disclosure, strict compliance with the requirements of 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 would be unduly burdensome for our Company as this would require additional work to be performed by us and our reporting accountants; and
- (e) our Directors are of the view that the Accountants’ Report covering the two years ended December 31, 2022, together with other disclosures in this document, has already provided the potential [REDACTED] with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company, and our Directors confirm that all information which is necessary for the [REDACTED] public to make an informed assessment of our Company’s business, assets and liabilities, financial position, trading position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interests of the [REDACTED] public.

WAIVER FROM STRICT COMPLIANCE WITH CLASS MEETING REQUIREMENTS AND ADDITIONAL REQUIREMENTS REGARDING ARTICLES OF ASSOCIATION APPLICABLE TO 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 listed 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 shares, securities convertible into shares, or options, warrants or similar rights to subscribe for shares or such convertible securities.

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

Paragraphs 56 and 65(a) of Rule 19A.42 of the Listing Rules provide that the content of a listing document for the listing of equity securities of a PRC issuer no part of whose share capital is already listed 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).

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 listing is or is to be on the Stock Exchange must include the Mandatory Provisions for Companies Listing Overseas (到境外上市公司章程必備條款) (the “**Mandatory Provisions**”) and other ancillary provisions.

On February 14, 2023, the State Council announced the implementation of 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) (collectively, the “**New PRC Regulations**”), which both took effect from March 31, 2023, and repealed the Special Regulations 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特別規定) and the Mandatory Provisions for Companies Listing Overseas (到境外上市公司章程必備條款), respectively.

Pursuant to the New PRC Regulations, PRC issuers shall formulate their 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 on Articles**”) issued by CSRC in place of the Mandatory Provisions, and as a result 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 and the Mandatory Provisions are no longer applicable. Accordingly, the requirements in relation to (i) class meetings for holders of domestic shares and H share under Rules 19A.25(1) and 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 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, insofar as PRC issuers are concerned.

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

As a PRC issuer, we have formulated our Articles of Association in line with the Guidelines on Articles under the New PRC Regulations. Pursuant to our Articles of Association, our Domestic Shares and H Shares are considered as one class of Shares, and there are no requirements for separate meetings of holders of Domestic Shares and H Shares to be conducted. Further, the Mandatory Provisions, having been repealed, have not been adopted in our Articles of Association.

As of the Latest Practicable Date, the Proposed Amendments had yet to be effective. Accordingly, we applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with Rules 19A.25(1), 19A.38 and 19A.45, paragraphs 56 and 65(a) of Rule 19A.42, and Section 1 of Part D of Appendix 13 to the Listing Rules, on the conditions that:

- (a) our Articles of Association are not inconsistent with the Guidelines on Articles and other applicable PRC laws and regulations; and
- (b) our Articles of Association are not inconsistent with (i) the Proposed Amendments as set out in the Consultation Paper, and (ii) the other provisions of the Listing Rules that are not subject to the Proposed Amendments.

CONTINUING CONNECTED TRANSACTIONS

We have entered into, and are expected to continue to engage in certain transactions which will constitute partially exempt continuing connected transactions and non-exempt continuing connected transactions of our Company under the Listing Rules upon the [REDACTED]. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], waivers from strict compliance with (i) the announcement, circular and independent Shareholders’ approval requirements under Rule 14A.105 of the Listing Rules; and (ii) the requirement of setting a monetary annual cap set out in Rule 14A.53 of the Listing Rules. Please see “Connected Transactions” of this document for further details of these transactions.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
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Chairman of the Board and non-executive Director

Mr. LIU Gexin (劉革新) ^{Note (1)}	Building 11, No. 1 Caotang Road Qingyang District, Chengdu Sichuan Province, PRC	Chinese
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Executive Directors

Dr. GE Junyou (葛均友)	No. 29 Qingyang Avenue Qingyang District, Chengdu Sichuan Province, PRC	Chinese
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Dr. WANG Jingyi (王晶翼)	903, Building 26, Hengda City No. 555 South Section of Fengxi Avenue Wenjiang District, Chengdu Sichuan Province, PRC	Chinese
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Non-executive Directors

Mr. LIU Sichuan (劉思川) ^{Note (1)}	Building 11, No. 1 Caotang Road Qingyang District, Chengdu Sichuan Province, PRC	Chinese
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Mr. FENG Hao (馮昊)	No. 2, 10th Floor, Building 5 No. 29 Tongzi Street Qingyang District, Chengdu Sichuan Province, PRC	Chinese
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Mr. ZENG Xuebo (曾學波)	Room 2402, No. 34 Shanhu Road No. 381, Shaxi Avenue Panyu District, Guangzhou Guangdong Province, PRC	Chinese
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Mr. LI Dongfang (李東方)	Room 301, Unit 7, Building 6 Yimingyuan, Chengnan Jiayuan Fengtai District Beijing, PRC	Chinese
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DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Independent non-executive Directors		
Dr. ZHENG Qiang (鄭強)	16 Yucca Ct San Ramon California, USA	American
Dr. TU Wenwei (涂文偉)	Room 9B, Block 1 Tam Towers, 25 Sha Wan Drive Pokfulam Hong Kong	Chinese (Hong Kong)
Dr. JIN Jinping (金錦萍)	Room 201, Unit 1 Building 17 Anheyuan, Tianxiu Garden Haidian District Beijing, PRC	Chinese
Dr. LI Yuedong (李越冬)	Room 5-201 in A District of Longhu No. 419 of Jinfu Road Qingyang District, Chengdu Sichuan Province, PRC	Chinese

Note:

(1) Mr. LIU Sichuan is the son of Mr. LIU Gexin.

SUPERVISORS

Name	Address	Nationality
Mr. LAI Degui (賴德貴)	6-1-6-2, No. 10 Shuyuan Road Qingyang District, Chengdu Sichuan Province, PRC	Chinese
Ms. LIAO Yihong (廖益虹)	No. 99 Qingyang Avenue 28-1-#302 Qingyang District Chengdu Sichuan Province, PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Mr. WAN Peng (萬鵬)	No. 2 Longtengzheng Street Wuhou District, Chengdu Sichuan Province, PRC	Chinese
Dr. SONG Hongmei (宋宏梅)	No. 577 Bilin Street Pidu District, Chengdu Sichuan Province, PRC	Chinese
Ms. YANG Qiuyan (楊秋艷)	Jinhe Valley Phase 4 No. 191 Qixing Street Wenjiang District, Chengdu Sichuan Province, PRC	Chinese
Dr. QING Yan (卿燕)	Building 7, Jiazhaoye Longxi No. 977 Fengxi Avenue Wenjiang District, Chengdu Sichuan Province, PRC	Chinese

See the section headed “Directors, Supervisors and Senior Management” in this document for further details.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Goldman Sachs (Asia) L.L.C.

68/F, Cheung Kong Center
2 Queen's Road Central
Hong Kong

CITIC Securities (Hong Kong) Limited

18/F, One Pacific Place
88 Queensway
Hong Kong

[REDACTED]

Legal Advisors to our Company

As to Hong Kong law and United States law

Kirkland & Ellis

26th Floor, Gloucester Tower
The Landmark, 15 Queen's Road Central
Central
Hong Kong

As to PRC law

King & Wood Mallesons

18th Floor, East Tower
World Financial Center
1 Dongshanhuan Zhonglu
Chaoyang District
Beijing, PRC

As to PRC intellectual property law

Global Law Office

15 & 20/F Tower 1
China Central Place
No. 81 Jianguo Road
Chaoyang District
Beijing, PRC

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Legal Advisors to the Joint Sponsors and the [REDACTED]	<i>As to Hong Kong law and United States law</i> Sullivan & Cromwell (Hong Kong) LLP 20th Floor, Alexandra House 18 Chater Road, Central Hong Kong <i>As to PRC law</i> Zhong Lun Law Firm 22-31/F, South Tower of CP Center 20 Jin He East Avenue Chaoyang District Beijing, PRC
Independent Auditor and Reporting Accountants	KPMG <i>Certified Public Accountants</i> 8/F, Prince's Building 10 Chater Road Central Hong Kong
Industry Consultant	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co. Room 2504, Wheelock Square No. 1717 Nanjing West Road Jingan District Shanghai, PRC
Independent Property Valuer	Cushman & Wakefield Limited 27/F, One Island East, Taikoo Place 18 Westlands Road Quarry Bay Hong Kong
Compliance Adviser	First Shanghai Capital Limited 19/F, Wing On House 71 Des Voeux Road Central Hong Kong

[REDACTED]

CORPORATE INFORMATION

Head Office, Registered Office and Principal Place of Business in the PRC	No. 666 Xinhua Avenue Chengdu Cross-Strait Science and Technology Industry Development Park Wenjiang District, Chengdu Sichuan Province, PRC
Principal Place of Business in Hong Kong	5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Company’s Website	<u>www.kelun-biotech.com</u> <i>(the information contained on the website does not form part of this document)</i>
Joint Company Secretaries	Mr. ZHOU Zejian (周澤劍) Courtyard No.62 Tonglinge Road Xicheng District Beijing, PRC Ms. FUNG Wai Sum (馮慧森) <i>(ACG, HKACG)</i> 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Authorized Representatives	Dr. GE Junyou (葛均友) No. 29 Qingyang Avenue Qingyang District, Chengdu Sichuan Province, PRC Ms. FUNG Wai Sum (馮慧森) 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Audit Committee	Dr. LI Yuedong (李越冬) (<i>Chairperson</i>) Dr. TU Wenwei (涂文偉) Dr. JIN Jinping (金錦萍)

CORPORATE INFORMATION

Remuneration Committee

Dr. ZHENG Qiang (鄭強) (*Chairperson*)

Mr. LIU Sichuan (劉思川)

Dr. JIN Jinping (金錦萍)

Nomination Committee

Mr. LIU Gexin (劉革新) (*Chairperson*)

Dr. ZHENG Qiang (鄭強)

Dr. TU Wenwei (涂文偉)

[REDACTED]

Principal Banks

Industrial Bank Co., Ltd.

Chengdu Wenjiang Sub Branch

Room 1387-1393, Section 3

Guanghua Avenue

Wenjiang District, Chengdu

Sichuan Province, PRC

Bank of Communications Co., Ltd.

Xindu Sub Branch

1st Floor, Financial Center

No. 289 Ma Chao East Road

Xindu District, Chengdu

Sichuan Province, PRC

China CITIC Bank Corporation Ltd.

Chengdu Yingbin Avenue Sub Branch

No. 299 Yingbin Avenue

Jinniu District, Chengdu

Sichuan Province, PRC

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers, and from the independent industry report prepared by Frost & Sullivan (the “Frost & Sullivan Report”). We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, the Joint Sponsors, the [REDACTED], the [REDACTED], the Joint [REDACTED], the [REDACTED], the [REDACTED], any of 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.

GLOBAL AND CHINA’S PHARMACEUTICAL MARKETS

The global and China’s pharmaceutical markets have witnessed significant growth in recent years and are projected to grow at a rapid pace over the next decade. Driven by an aging population, growing R&D expenditure and technology advancements, the global pharmaceutical market grew from US\$1,208.4 billion in 2017 to US\$1,495.0 billion in 2022 at a CAGR of 4.3% and is projected to reach US\$2,090.8 billion in 2030 at a CAGR of 4.3% from 2022. Meanwhile, the pharmaceutical market in China grew from RMB1,430.4 billion in 2017 to RMB1,554.1 billion in 2022 at a CAGR of 1.7% and is anticipated to reach RMB2,624.5 billion in 2030 at a CAGR of 6.8% from 2022. Once dominated by generic drugs, China’s pharmaceutical landscape has undergone significant development with the innovative drug market expanding rapidly in recent years. Following the implementation of favorable government policies for drug innovation, China has witnessed a significant growth in NDAs granted by the NMPA for innovative drugs, from one in 2017 to 47 in 2021. Accordingly, China’s patented drug market grew from RMB799.0 billion in 2017 to RMB958.9 billion in 2022 at a CAGR of 3.7%, and is projected to grow at a faster pace and reach RMB1,972.5 billion by 2030 at a CAGR of 9.4% from 2022.

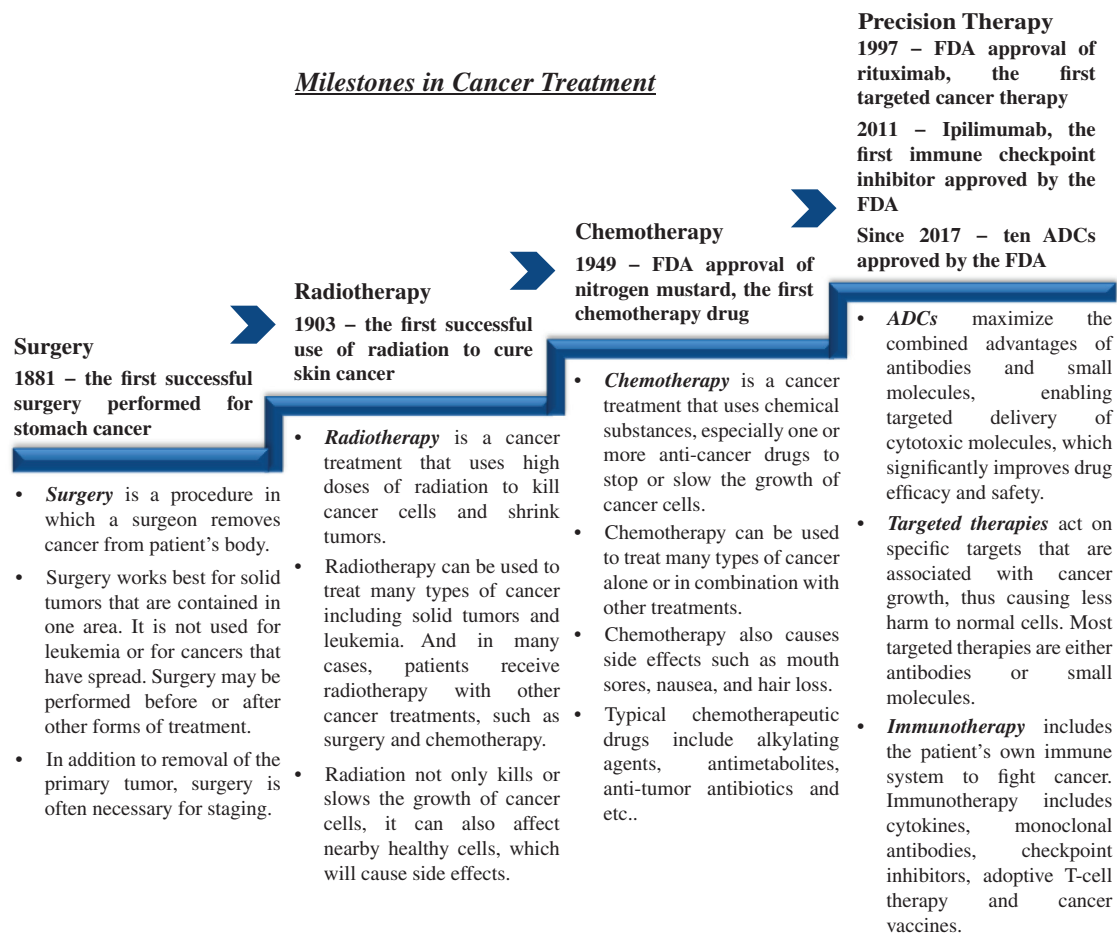
THE ONCOLOGY DRUG MARKET

Overview

Cancer is a broad group of diseases in which abnormal cells grow in an uncontrolled manner and spread locally or to distant parts of the body. Cancer is the leading cause of mortality worldwide with 10.5 million deaths globally and 2.9 million deaths in China in 2022, and its disease burden is expected to climb as a result of population growth and aging. Global cancer incidence was 20.2 million in 2022 and is projected to reach 24.5 million in 2030. In China, the total cancer incidence was 4.8 million in 2022 and is expected to reach 5.8 million in 2030.

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Cancer treatment has evolved rapidly over the past few decades. As illustrated in the diagram below, the landscape of cancer treatment has progressed from surgery and indiscriminate cytotoxic treatments, such as radiotherapy and chemotherapy, to precision therapy, with antibody-based drugs including mAbs, bsAbs and ADCs being a major category. Notably, ADCs are one of the fastest-growing treatment modalities in recent years, progressing from a late-line treatment in selected blood cancers to a promising early-line therapeutic modality for broader solid tumor indications and beyond.



Source: Literature research, Frost & Sullivan

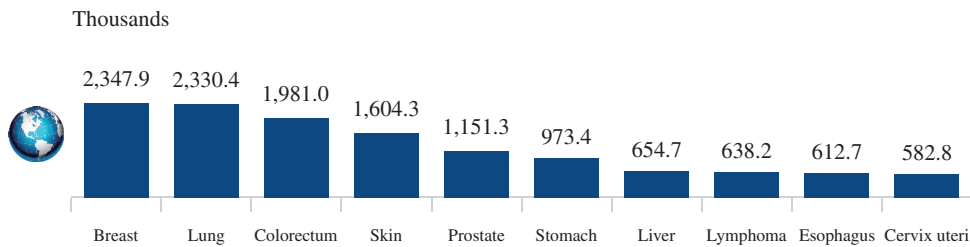
In 2022, targeted therapy and immunotherapy were the two largest oncology drug classes globally with a 61.3% and 24.5% market share, respectively, followed by chemotherapy (14.2%). In China, the development of targeted therapy and immunotherapy has lagged behind other major markets such as the U.S. In 2022, China’s oncology drug market was dominated by chemotherapy with a 54.3% market share, while targeted therapy and immunotherapy only occupied 37.0% and 8.7% of the market, respectively.

INDUSTRY OVERVIEW

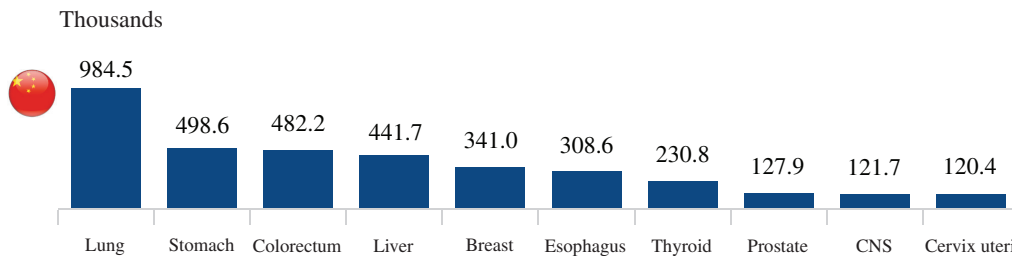
Top Ten Cancer Types Globally and in China

As illustrated in the charts below, China has an overlapping but different profile of top ten cancers by incidence compared to that globally, with LC, GC and CRC being the most common cancer types. Despite the differences in ranking, several cancer types are among the top ten cancers by incidence both globally and in China, including BC and LC, indicating vast addressable patient populations for these cancer types both globally and in China.

Top 10 Cancers by Incidence Globally, 2022



Top 10 Cancers by Incidence China, 2022



Source: Globocan, IARC, NCCR, Frost & Sullivan

Market Size

The global and China’s oncology drug markets have expanded rapidly in recent years. The global oncology drug market rose from US\$110.6 billion in 2017 to US\$205.1 billion in 2022 at a CAGR of 13.1% and is projected to reach US\$458.6 billion in 2030 at a CAGR of 10.6% from 2022. The oncology drug market in China grew from RMB139.4 billion in 2017 to RMB233.6 billion in 2022 at a CAGR of 10.9% and is forecasted to continue its strong growth, reaching RMB586.6 billion in 2030 at a CAGR of 12.2% from 2022.

INDUSTRY OVERVIEW

Market Drivers and Future Trends

The growth of the oncology drug market is driven primarily by the following factors:

Expanding Patient Pool with Significant Medical Needs. Together with population growth and aging demographic, advances in early-stage diagnosis and improving survival rates have substantially increased the oncology patient pool, which has in turn driven the expansion of the oncology drug market globally. In China, the outcomes of oncology patients, despite the improvements witnessed in recent years, still lag behind those in developed countries. In part due to the relatively limited availability of more advanced treatment modalities such as ADCs, the five-year survival rate of cancer patients in China (40.5%) was substantially lower compared to those in the U.S. (67.1%) in 2015. Survival for advanced cancer patients, in particular, remains poor despite recent advances in targeted and immunotherapies, as existing modalities are limited by drug resistance and risks of serious side effects, with limited effective treatment options available to late-line patients. This indicates a significant medical need for more innovative therapies to improve cancer prognosis and outcome. As set out in its Healthy China Action (2019-2030) (《健康中國行動(2019-2030)》), China is committed to raising the overall five-year survival rate of cancer patients to 46.6% by 2030.

Increasing Medical Expenditure. The global economy experienced rapid growth in the past two decades. Higher disposable income per capita has made it easier for patients to afford treatments. In particular, medical expenditures per capita in China increased from approximately RMB3,756.7 in 2017 to RMB5,348.1 in 2021, having expanded at a robust CAGR of 9.2%. This factor is expected to continue enhancing Chinese patients’ ability and willingness to pay for more advanced and expensive treatments options, especially for life-threatening diseases like cancers.

Improved Reimbursement Environment. Enhancing the affordability of medical treatments has increasingly become a policy priority for regulators worldwide. Recent reforms in government-sponsored medical insurance schemes in China, in particular, have lowered the cost and improved the affordability of oncology treatments to Chinese residents. Following the implementation of the dynamic adjustment mechanism in 2017, the national reimbursement drug list (NRDL) had witnessed a rapid growth in the number of oncology drugs admitted via price negotiation, from only two in 2016 to 14 in 2022 while showing increased flexibility and shortened time intervals between each round of negotiation. This has substantially improved patients’ access to potentially life-saving oncology medicines, which drives demand and, in turn, growth of the oncology drug market.

Favorable Government Policies Driving Innovation. Government support has driven and will continue to drive oncology research and development. One of China’s major goals is to reshape the industry from developing “me too” or “me better” drugs and relying on drug in-licensing to one that fosters and promotes end-to-end innovation. The “Fourteenth Five-Year Plan for National Economic and Social Development of the PRC and the Outline of Vision Goals for 2035 (《中華人民共和國國民經濟和社會發展第十四個五年規劃和2035年遠景目標綱要》)” released in 2021 continues to emphasize the central role of innovation in China’s

INDUSTRY OVERVIEW

modernization progress, and the significance of R&D breakthrough in medical science. After launching its priority review mechanism in 2016, the NMPA has further streamlined NDA review procedures, which contributed to a significant growth in NDAs granted for Class 1 innovative drugs. For more details on China’s recent healthcare reform, see “Regulatory Overview – Laws and Regulations in Relation to New Drugs.”

The oncology drug market is expected to be influenced by the following trends:

Shifting Treatment Paradigm and Emergence of New Modalities. As a global trend, an increasing number of targeted therapy and immunotherapy drugs with improved clinical efficacy and safety have displaced or been added alongside chemotherapy as standard treatments. Deepening insights into cancer biology and advances in engineering technologies have propelled the development of novel treatment modalities such as ADCs that improve upon the clinical efficacy and safety of more traditional therapies. Despite their improved clinical benefits, the approved novel treatment modalities, such as TROP2 and HER2 ADCs, are still limited by drug resistance and notable safety concerns, leaving many patients underserved. Therefore, there is a significant unmet need for emerging modalities with differentiated or better efficacy and safety profiles, which are expected to transform the treatment paradigm of many cancer indications. In China, the market shares of targeted therapies and immunotherapies are forecasted to reach 45.9% and 39.9% by 2030, respectively, overtaking chemotherapy as the major cancer treatment modalities.

Increasing Use of Combination Therapy. Combination therapy, which uses two or more therapies with distinct mechanisms of actions, has become increasingly common as it can target cancers from multiple approaches simultaneously with potentially superior efficacy relative to monotherapies. The development of novel treatment modalities is expected to result in a greater number and variety of combination treatments.

Precision Medicine. Due to tumor heterogeneity, precision medicine tailored to each patient is critical for effective cancer treatment. Advances in genomic profiling have enabled more accurate characterization of a patient’s tumor. This, combined with a deeper understanding of disease biology, has empowered the development of precision therapies, highlighted by an increasing number of targeted therapy and immunotherapy based on targetable biomarkers. Some of these biomarker-driven therapies have demonstrated robust clinical benefits across multiple tumor types that share the same genomic alterations, leading to broad indication approvals, such as PD-(L)1 inhibitors that target patients with certain immunotherapy biomarkers and ADCs that target TROP2 and HER2 overexpression across a wide range of solid tumors. Rapidly evolving genomic technologies are expected to accelerate the translation of biomarker discoveries into novel targeted therapy and immunotherapy that may continue to transform treatment paradigm.

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Managing Cancer as a Chronic Disease. With therapeutic advances over the years, many cancers can now be controlled with treatments for months or even years. Patients previously without effective treatments, especially those diagnosed at an advanced stage, are now more likely to benefit from increasing treatment options. The need for managing cancer as a chronic disease effectively calls for innovative therapies with optimized balance between safety and efficacy, as well as differentiated mechanisms of action that may overcome drug resistance to existing treatments to prolong disease control.

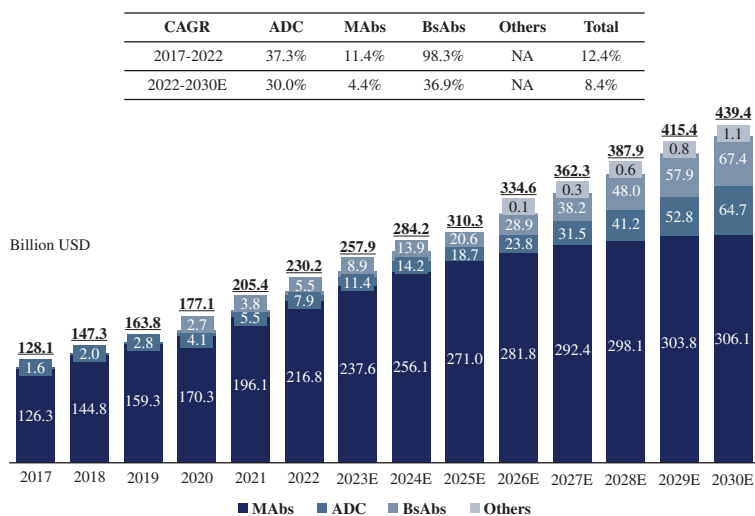
THE ANTIBODY-BASED DRUG MARKET

The antibody-based drug market covers antibody-based drugs for oncology and non-oncology indications. Antibody-based drugs are the largest category of biologics with generally higher efficacy and fewer side effects than conventional chemical drugs, such as chemotherapy, as antibody-based drugs are designed to engage specific molecular targets involved in disease pathogenesis, with potentially reduced harmful effects on non-target cells. Key categories of antibody-based drugs include mAbs, ADCs and bsAbs.

Global and China’s Market Size of Antibody-based Drugs

The global antibody-based drug market grew at a CAGR of 12.4% from US\$128.1 billion in 2017 to US\$230.2 billion in 2022. It is expected to continue its rapid growth in the coming years, reaching US\$439.4 billion in 2030 at a CAGR of 8.4%. Driven by a growing patient population, strong government support and continuous R&D activities, the antibody-based drug market in China grew from RMB11.8 billion in 2017 to RMB75.9 billion in 2022 at a CAGR of 45.1% and is expected to reach RMB479.3 billion in 2030 at a CAGR of 25.9% from 2022. The charts below show the growth of the global and China antibody-based drug markets.

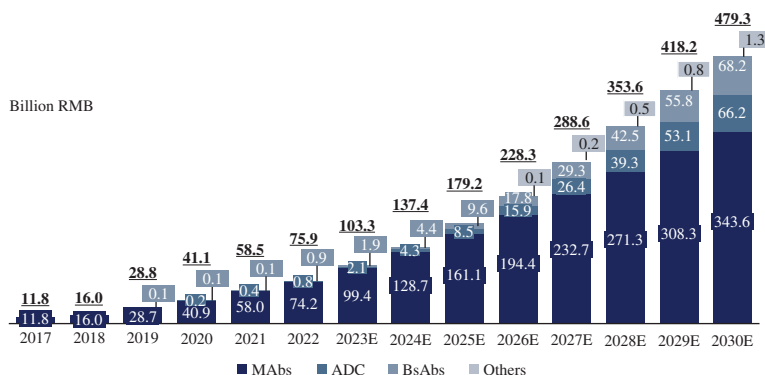
Historical and Forecasted Market Size of Antibody-based Drug Market Globally, 2017-2030E



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Historical and Forecasted Market Size of Antibody-based Drug Market in China, 2017-2030E

CAGR	ADC	MAbs	BsAbs	Others	Total
2017-2022	NA	44.5%	N/A	N/A	45.1%
2022-2030E	72.8%	21.1%	72.8%	N/A	25.9%



Source: FDA, NMPA, annual report, MOHRSS, Frost & Sullivan

As of the Latest Practicable Date, mAbs were the largest class of antibody-based drugs in China, with a market size of RMB74.2 billion in 2022. New generations of antibody-based drugs such as ADCs and bsAbs hold vast therapeutic potential. The ADC and bsAb markets are expected to experience substantial growth in the near future, faster than the overall antibody-based drug market, as more drug candidates obtain approval.

Comparison of Different Antibody-based Drugs

Among the major types of antibody-based drugs, ADC is an advanced modality that is differentiated from traditional chemotherapy and targeted drugs, as well as other antibody-based therapies. By combining the target selectivity of antibodies with the cell-killing potency of highly cytotoxic drugs, ADCs enable the selective delivery of cytotoxic drugs to the tumor. Compared to chemotherapy, ADCs potentially have a wider therapeutic window as they enable targeted delivery of payloads with much higher cytotoxicity to the tumor site than standard chemotherapy drugs, while reducing toxicity to healthy cells. Compared to other antibody-based drugs and targeted therapies, which heavily rely on the expression and biological effects of the target antigen(s), ADCs can potentially bring enhanced efficacy and overcome treatment resistance as they primarily exert anti-tumor effect via the cytotoxic payloads they are equipped with. This differentiated mechanism allows ADCs to better overcome low or heterogeneous antigen expression in tumors, which is a major cause of treatment resistance to other antibody-based drugs and targeted therapies. The potential of ADCs to overcome treatment resistance is supported by the approved use of ADCs for late-line patients who have failed other antibody-based drugs or targeted therapies.

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A comparison of ADCs, bsAbs and mAbs is set forth in the table below:

	ADC	BsAb	MAb
Characteristic	Composed of an antibody linked to a biologically active cytotoxic drug.	Simultaneously bind to two different epitopes or antigens.	Made by identical immune cells that are all clones of a unique parent cell.
Advantages	Compared to chemotherapy, ADCs potentially have a wider therapeutic window as they enable targeted delivery of payloads with much higher cytotoxicity than standard chemotherapy drugs to the tumor site while reducing toxicity to healthy cells; Compared to other antibody-based drugs and targeted therapies, ADCs potentially have (i) enhanced efficacy as ADCs exert anti-tumor effects primarily via highly potent payloads and bystander effect, which may overcome low or heterogeneous antigen expression in tumors; (ii) more options to target as ADCs do not necessarily require the target antigen to have any biological effects, unlike mAbs.	BsAbs’s dual specificity potentially allows for (i) enhanced tumor killing via redirecting immune cells to tumor cells, (ii) concurrent blockade of distinct pathways with unique/overlapping functions, and (iii) increased binding capability by interacting with two different cell-surface targets instead of one.	Proven clinical activity for various diseases, notably cancers and autoimmune diseases.
Limitations	Complex drug design and difficulties in manufacturing to produce ADCs with optimized parameters, including target selection, antibodies, payloads and the payload-linker linkage.	Complexity in manufacturing and selecting the optimal molecular design to fit the proposed mechanisms of action; Potentially lower dosing flexibility due to the fixed ratio, i.e., relative dose, of the two component antibodies.	More likely to encounter drug resistance due to the heterogeneous antigen distribution within the same tumor, or experience low treatment response rates due to heterogeneous antigen expression between tumors from different patients.

Source: Literature review, Frost & Sullivan

The ADC Market

Overview

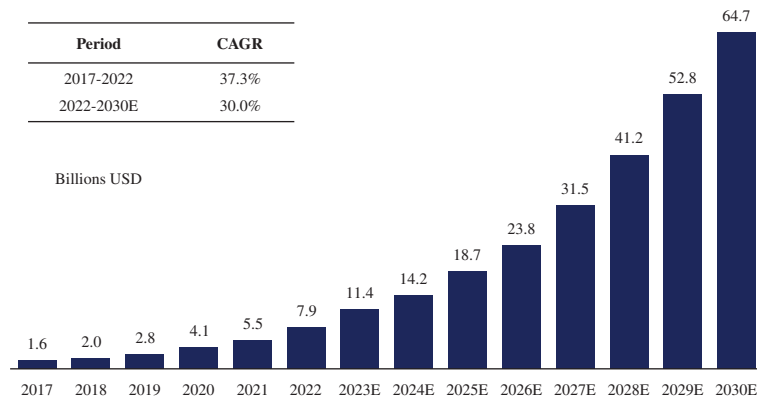
ADCs are one of the fastest-growing treatment modalities for cancer. They combine the target selectivity of antibodies and the cell-killing potency of highly cytotoxic drugs. Classic chemotherapy, the mainstay of anti-cancer treatment, demonstrates limited selectivity against cancer cells, frequently resulting in intolerable systemic toxicity. Like guided missiles, ADCs are designed to utilize an antibody to deliver cytotoxic drugs selectively to tumor cells. This combinatorial design potentially reduces off-target toxicity while allowing the use of highly potent cytotoxic drugs that would otherwise be intolerable in systemic therapies, thereby leading to improved therapeutic window and efficacy.

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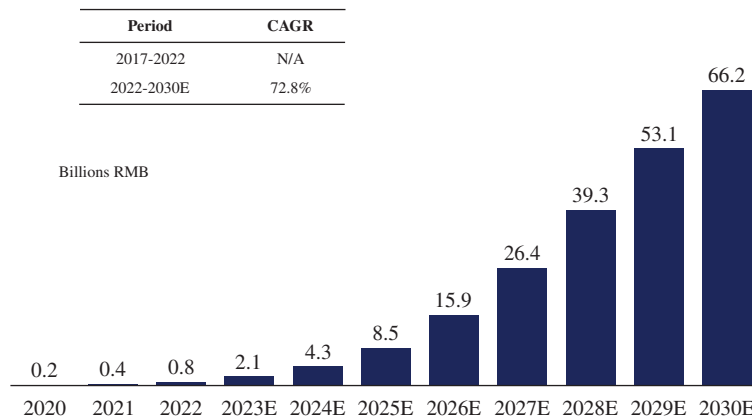
Global and China’s Market Size of ADCs

The global ADC market size grew rapidly from US\$1.6 billion in 2017 to US\$7.9 billion in 2022 at a CAGR of 37.3% and is projected to continue its robust growth at a CAGR of 30.0% from 2022 to 2030. China’s ADC market started to grow, following the approval of the first ADC, Kadcyła, by the NMPA in 2020, and is expected to increase from RMB0.8 billion in 2022 to RMB66.2 billion at a CAGR of 72.8%.

Historical and Forecasted Global ADC Market Size, 2017-2030E



Historical and Forecasted China ADC Market Size, 2020-2030E

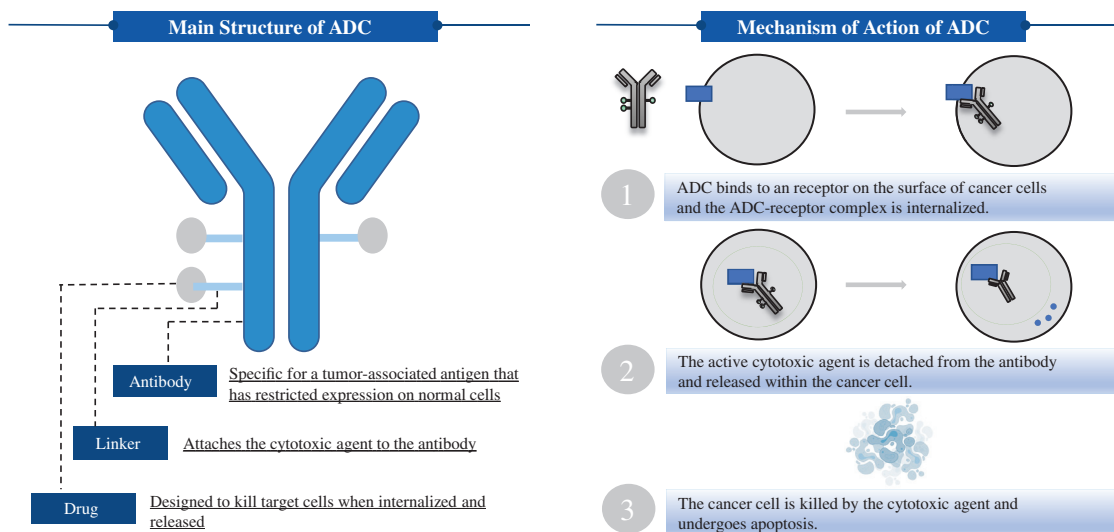


Source: FDA, NMPA, annual report, MOHRSS, Frost & Sullivan

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ADC Drug Design

ADCs comprise three core components: an antibody that binds to a specific target, a cytotoxic agent known as the payload, and a linker connecting the two. These components can be designed to influence the pharmacological and clinical profiles of the ADC. The following diagram illustrates an ADC’s structure and its canonical mechanism of action:



Source: Frost & Sullivan

Despite their vast therapeutic potential, early generations of ADCs faced various challenges, including toxicities and suboptimal efficacy that stymied numerous ADC development programs from the 1980s to the 2000s. These challenges were largely associated with the complex drug design of ADCs, which requires thoughtful combination of antibodies, linkers and payloads in the context of a defined target, cancer indication and its associated microenvironment.

Major considerations in ADC design are discussed below:

- **Antibody and Target Selection.** The target affinity, internalization efficiency, solubility, circulation half-life, and immunogenicity of the antibody are important factors to consider. An ideal antibody target should be a tumor-associated antigen, a cell surface protein preferentially expressed in tumors versus healthy tissues. Examples of clinically validated targets include TROP2, HER2 and Nectin-4, which are overexpressed in a broad range of cancers.
- **Payloads.** The cytotoxic potency, mechanism of action and cell permeability of the payload are key features for consideration. Most FDA-approved ADCs carry payloads with much higher cytotoxicity than standard chemotherapy drugs. These payloads usually trigger cell death by interrupting DNA replication, e.g., topoisomerase I (TOPO1) inhibitors, or by disrupting the cell’s skeleton, e.g.,

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microtubule destabilizers. The cell permeability of payloads determines how well the detached payloads can diffuse from within cells that express the target antigen into neighboring cells, where the payload can exert a cytotoxic effect independent of target antigen expression, i.e., bystander killing.

- Linker. Linkers dictate how and when the payload is released from the ADC and can be broadly categorized as non-cleavable and cleavable. Non-cleavable linkers are associated with less off-target toxicity and bystander effect as payload release occurs only after ADC internalization and intracellular antibody degradation, whereas cleavable linkers tend to offer greater versatility as diverse biological cues commonly found in tumor microenvironment, such as low pH, can be used to trigger payload release. Both types of linkers have their respective advantages and limitations and each can be modified to balance efficacy and undesired toxicity. For example, Kadcyła’s MCC linker, due to its non-cleavable nature, prevents the linker-payload moiety from crossing the cell membrane, which limits bystander effect and potentially contributes to drug resistance. Alternative linkers, such as the cleavable Val-Cit linker used by A166, potentially overcome such drug resistance mechanism by enabling the linker to be degraded, which allows payload release and diffusion across cell membrane to exert bystander effect.
- DAR and Conjugation Technology. Another important factor to consider when designing ADCs is DAR, i.e., the number of payloads conjugated to one antibody. Attaching too few payload molecules may result in insufficient efficacy, while attaching too many will destabilize the ADC, altering its PK profile, inducing plasma clearance and increasing systemic toxicity. Conjugation technology is another major factor in the successful design of ADCs. Compared to site-specific conjugation technology, non-site-specific conjugation technology offers greater ease of use but results in a heterogeneous mixture of ADCs with variable numbers of payloads attaching to each antibody. This product heterogeneity can lead to inconsistent PK profiles that may adversely affect the efficacy and safety of the drug. In contrast, by engineering specific sites onto mAbs for connecting payload-linker groups, site-specific conjugation technology enables the generation of homogeneous ADCs with a pre-specified, desired DAR, which potentially improves ADC activity.

The complex design of ADCs also poses a high demand on manufacturing capabilities, as it requires advanced manufacturing suites with specialized equipment, deep analytical know-how and careful handling techniques to accurately characterize each of the ADC components and ensure the purity, stability and DAR of the final product.

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The following table illustrates the respective ADC design of SKB264 and A166 alongside that of Trodelvy and DS-1062, two TROP2 ADCs at phase 3 stage or beyond, as well as Kadcyla, Aidixi and Enhertu, three FDA and/or NMPA-approved HER2 ADCs as of the Latest Practicable Date.

ADC design of TROP2 ADCs (SKB264, Trodelvy and DS-1062)

	SKB264	Trodelvy	DS-1062
Antibody	Sacituzumab	Sacituzumab	Datopotamab
Linker	2-methylsulfonyl pyrimidine-containing CL2A linker	Maleimide-containing CL2A linker	GGFG linker
Payload	KL610023, a belotecan derivative	SN-38, a water-soluble metabolite of irinotecan	Deruxtecan, an Exatecan derivative
Conjugation	Irreversible site-specific methylsulfonyl pyrimidine-thiol conjugation	Reversible site-specific maleimide-thiol conjugation	Reversible site-selective maleimide-thiol conjugation
Overall DAR	7.4	7.6	4
Major differentiation of SKB264 vs. Trodelvy/DS-1062	/	<ul style="list-style-type: none"> SKB264’s improved plasma stability due to irreversible linker-mAb conjugation and differentiated payload structure 	<ul style="list-style-type: none"> SKB264’s favorable ADC hydrophilicity even at a higher DAR value due to the more hydrophilic CL2A linker SKB264’s minimal risk of ILD toxicity associated with KL610023

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ADC design of HER2 ADCs (A166, Kadcyra, Aidixi and Enhertu)

	A166	Kadcyla	Aidixi	Enhertu
Antibody	Trastuzumab	Trastuzumab	Disitamab	Trastuzumab
Linker	Val-Cit linker	MCC linker	Val-Cit linker	GGFG linker
Payload	Duo-5, a MMAF derivative and a highly toxic tubulin inhibitor	DM1, a maytansine derivative and a highly toxic tubulin inhibitor	MMAE, a highly toxic tubulin inhibitor	Deruxtecan, an Exatecan derivative and a moderately toxic TOPO I inhibitor
Conjugation	Stable site-specific lysine conjugation	Stochastic lysine conjugation	Reversible non-site-specific cysteine conjugation	Reversible site-specific cysteine conjugation
DAR	2	3.5	4	8
Major differentiation of A166 vs. Kadcyra/ Aidixi/Enhertu	/	<ul style="list-style-type: none"> A166’s greater ADC homogeneity due to site-specific conjugation A166’s bystander effect due to enzyme-cleavable linker with cell membrane permeable payload 	<ul style="list-style-type: none"> A166’s greater ADC homogeneity due to site-specific conjugation A166’s improved plasma stability due to stable linker-mAb conjugation 	<ul style="list-style-type: none"> A166’s minimal risk of ILD toxicity associated with Duo-5 A166’s improved plasma stability due to stable linker-mAb conjugation

Source: Frost & Sullivan

Market Drivers and Future Trends of ADC Development

Advances in ADC Design and Conjugation Technologies. ADCs have recently begun to gain momentum after two decades of trial and error after its first approval in 2000 by the FDA, encouraged by the successful launch of new drugs with outstanding clinical outcomes, such as Enhertu (HER2-directed) and Padcev (Nectin-4-directed) in 2019 and Trodelvy (TROP2-directed) in 2020. In particular, ongoing research on ADC technology and cancer biology is expected to drive the discovery of novel molecular targets and payload molecules,

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as well as better linker design and conjugation technologies, potentially yielding new designs that improve the therapeutic effects of ADCs and reduce the toxicity issues that limit the use of currently marketed ADCs. Leveraging the continuous advancement in ADC design and conjugation technologies, with a total of 12 FDA-approved ADCs to date, ADCs have progressed from a late-line treatment in selected blood cancers to a promising early-line therapeutic modality for broader solid tumor indications and beyond.

Expansion of Indications and Treatment Lines. Advancement in ADC technologies is expected to result in a broader range of potential molecular targets and indications, including in non-oncology areas such as autoimmune diseases. ADCs are also expected to enter earlier treatment lines and expand into the early stages of cancers with larger addressable patient populations.

Combination with Other Treatment Modalities. The mechanisms of action of ADCs may synergize with other treatment modalities to potentiate tumor cell killing. For instance, combination therapies with ADCs and immune checkpoint inhibitors have shown promise in clinical studies in enhancing anti-tumor efficacy.

Growing Needs for Fully Integrated Capabilities. The R&D of ADCs requires extensive biological, chemical and manufacturing know-how and capabilities that span across biologics, small molecules and bioprocessing. The increasing development and manufacturing needs for ADCs are expected to benefit biopharmaceutical companies with fully integrated end-to-end capabilities that enable the rapid advancement of ADC candidates.

The BsAb Market

BsAbs are an emerging treatment modality that concurrently binds two distinct epitopes or antigens. Their dual specificity potentially enables multiple synergistic functions previously unattainable by using mAbs alone, while offering reduced treatment cost, simplified treatment regimen/administration and improved safety compared to combination therapies with two mAbs.

Given the promising therapeutic potential of bsAbs, the global market of bsAbs grew at a CAGR of 98.3% from 2017 to 2022 with ten marketed products as of the Latest Practicable Date, and it is expected to further expand to US\$67.4 billion by 2030 at a CAGR of 36.9% from 2022. As bsAbs development requires extensive end-to-end capabilities that span from antibody engineering and technology platform to bioprocessing, there were no bsAbs on the market in China until 2020. The bsAb market in China was estimated to be about RMB0.9 billion in 2022 with only three approved products as of the Latest Practicable Date. However, with the maturation of bsAb technology platforms, anticipated launch of more bsAbs and potential indication expansion, the bsAb market in China is expected to increase to RMB68.2 billion in 2030 at a CAGR of 72.8% from 2022.

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The MAb Market

MAbs are a major class of targeted therapy that specifically binds to a designated epitope on a target protein. Since their first approval by the FDA in 1986, mAbs have transformed treatment paradigm, enabling many diseases such as cancer to be treated in a more targeted way.

As the predominant treatment modality for various diseases, the global market for mAbs grew rapidly at a CAGR of 11.4% from 2017 to 2022 and is projected to reach US\$306.1 billion by 2030 at a CAGR of 4.4% from 2022. The mAb market in China increased at a CAGR of 44.5% from 2017 to 2022 and is forecasted to reach RMB343.6 billion by 2030 at a CAGR of 21.1% from 2022.

GLOBAL AND CHINA’S TROP2 ADC MARKETS

Overview

TROP2 is a transmembrane protein that has essential functions in embryonic and organ development with low expression in normal tissues. Across a broad spectrum of cancers, TROP2 is frequently overexpressed and promotes cancer proliferation, invasion and metastasis.

TROP2 is a clinically valuable ADC target as it is overexpressed with low heterogeneity in a wide range of highly prevalent or hard-to-treat cancers, including advanced tumors with limited actionable targets. TROP2 ADCs have also demonstrated synergistic anti-tumor activity in various preclinical and clinical studies as the backbone of potential combination therapies with other treatment modalities such as chemotherapy, targeted therapy and immunotherapy.

As of the Latest Practicable date, Gilead Sciences’ TROP2 ADC Trodelvy was the only approved TROP2-directed drug globally. Despite its promising clinical activity, Trodelvy is associated with severe neutropenia (i.e., a lower-than-normal number of neutrophils in the blood) and severe diarrhea, two serious adverse reactions for which Trodelvy has black box warnings issued by the FDA. Consequently, there is a high unmet need for novel TROP2 ADCs that have limited toxicities while maintaining robust anti-tumor activity.

Addressable Market Size of TROP2 ADCs

The table below highlights the major cancers in which TROP2 is frequently overexpressed. They include some of the most prevalent or hard-to-treat cancers such as BC (including TNBC and HR+/HER2-BC), NSCLC, GC, OC, CRC, urothelial cancer (UC), PC, cervical cancer (CC), castrate-resistant prostate cancer (CRPC), head and neck squamous cell carcinoma (HNSCC), and endometrial cancer (EC), indicating significant market potential for novel TROP2 ADCs. Notably, TROP2 has one of the highest overexpression rates in BC (including TNBC and HR+/HER2- BC) and NSCLC, the lead indications of SKB264. Other

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than SKB264, Gilead Sciences’ Trodelvy and Daiichi Sankyo’s DS-1062 were the only two TROP2 ADCs in phase 3 stage or beyond globally that target the same lead indications as SKB264 as of the Latest Practicable Date. See “– Global and China’s TROP2 ADC Markets – Competitive Landscape of the Global TROP2 ADCs Market” for further details.

Indication	Overexpression ⁽¹⁾
BC ⁽²⁾	80%
NSCLC	64% to 75%
GC	56%
OC	59%
CRC	68%
UC	83%
PC	55%
CC	88.7%
CRPC	89%
HNSCC	42.9%
EC	84%

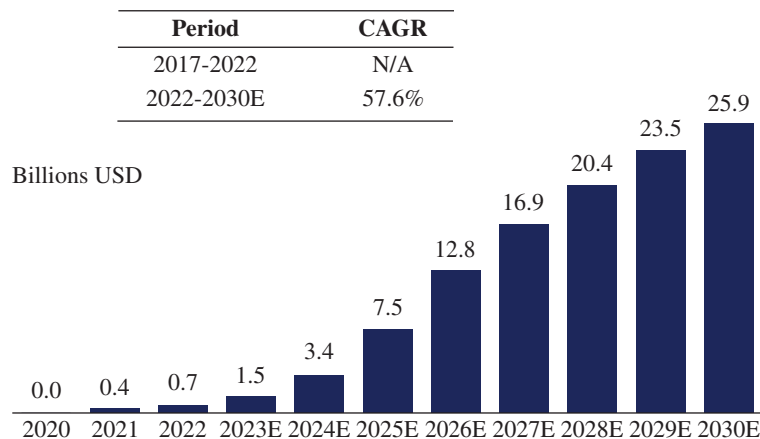
Notes:

- (1) “Overexpression” refers to the proportion of patients with TROP2 overexpression for a given indication;
- (2) TNBC: 88%; HR+/HER2- BC: significantly higher TROP2 expression than other HER2+ subtypes.

Source: Literature review, Frost & Sullivan

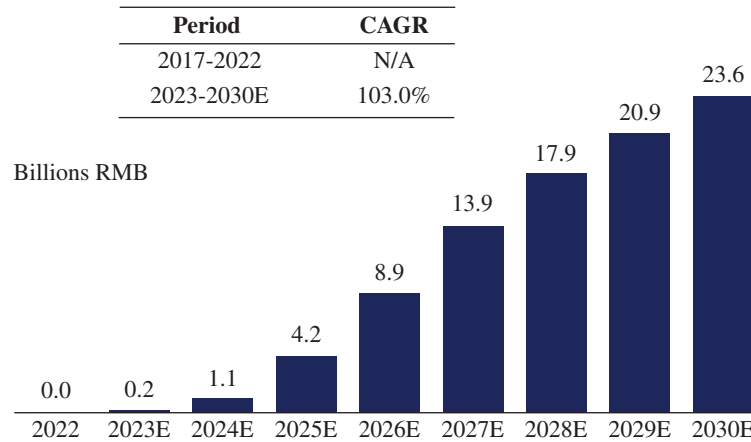
As shown in the charts below, the global TROP2 ADC market was US\$0.7 billion in 2022 and is expected to reach US\$25.9 billion in 2030 at a CAGR of 57.6% from 2022. The TROP2 ADC market in China is expected to grow, following the approval of the first TROP2 ADC, Trodelvy, by the NMPA in 2022, and is expected to reach RMB23.6 billion in 2030 at a CAGR of 103.0% from 2023.

Global TROP2 ADCs Market Size, 2020-2030E



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China TROP2 ADCs Market Size, 2022-2030E



Source: FDA, NMPA, annual report, MOHRSS, Frost & Sullivan

TNBC

BC is the most prevalent type of cancer worldwide. TNBC is an aggressive subtype of BC, representing approximately 15% of total BC cases globally and in China. It is characterized by the absence of estrogen, progesterone and HER2 receptors, three actionable targets commonly found in other subtypes of BC. TNBC is associated with a worse prognosis compared to other BC subtypes and about 85% of TNBC patients present with advanced disease at the time of diagnosis, with a five-year survival rate of about 12%. TROP2 is overexpressed in approximately 88% of TNBC patients.

Incidence

Globally, the incidence of TNBC grew from 306.7 thousand in 2017 to 352.2 thousand in 2022 and is projected to reach 408.8 thousand in 2030. In China, the incidence of TNBC increased from 47.3 thousand in 2017 to 51.2 thousand in 2022 and is expected to reach 55.6 thousand in 2030.

Treatment Paradigm

Chemotherapy, immunotherapy and targeted therapy are the recommended treatment options for treating advanced TNBC in the U.S. and China. As of the Latest Practicable Date, Trodelvy was the only approved TROP2 ADC for advanced TNBC in the U.S. and China.

In the U.S., the first-line and beyond (1L+) treatments for advanced TNBC include single-agent chemotherapy or doublet chemotherapy that combines two chemotherapy drugs, chemoimmunotherapy that combines chemotherapy with PD-1 inhibitor for PD-L1-positive (PD-L1+) patients, and poly (ADP-ribose) polymerase (PARP) inhibitor for patients with deleterious BRCA mutations. For adult patients with metastatic TNBC who have received at least two prior therapies with at least one line for metastatic disease, Trodelvy is approved as a 3L+ treatment.

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In China, the 1L treatments for advanced TNBC involve either single-agent or doublet chemotherapy. The 2L treatment options consist of single-agent chemotherapy and combination therapy including chemoimmunotherapy with PD-(L)1 inhibitor, doublet chemotherapy and chemotherapy with anti-angiogenic mAb bevacizumab. For patients who progress during or after 2L treatments, 3L+ treatment options include TROP2 ADC Trodelvy, liposome-encapsulated chemotherapy, and PARP inhibitor for patients with deleterious BRCA mutations.

Despite the survival benefits brought by chemoimmunotherapy and PARP inhibitor therapy, they are only beneficial for advanced TNBC patients with PD-L1 expression and deleterious BRCA mutations, representing only 20% and 10-20% of the total advanced TNBC patient population, respectively. Although the recent approval of Trodelvy (TROP2 ADC) as a 3L+ treatment improves survival in heavily pre-treated patients with advanced TNBC, many patients are unresponsive or develop resistance to Trodelvy. Moreover, the FDA issued a black box warning for Trodelvy for severe neutropenia (i.e., a lower-than-normal number of neutrophils in the blood) and severe diarrhea. Consequently, there is a substantial unmet need for safe and effective treatments.

HR+/HER2- BC

HR+/HER2- BC is the most prevalent subtype of BC, accounting for approximately 55% of total BC cases worldwide. About 5-10% of HR+/HER2- BC patients are diagnosed with advanced disease, with a five-year survival rate of about 30%. HR+/HER2- BC is reported to have significantly higher TROP2 expression than HER2+ BC.

Incidence

Globally, the incidence of HR+/HER2- BC rose from 1.1 million in 2017 to 1.3 million in 2022 and is forecasted to reach 1.5 million in 2030. In China, the incidence of HR+/HER2- BC increased from 173.4 thousand in 2017 to 187.6 thousand in 2022 and is expected to reach 203.8 thousand in 2030.

Treatment Paradigm

Endocrine therapies, such as aromatase inhibitors (AIs) and a selective ER degrader (SERD) represent the cornerstone of standard treatments for advanced HR+/HER2- BC in the U.S. and China. As of the Latest Practicable Date, Trodelvy was the only TROP2 ADC approved for treating advanced HR+/HER2- BC in the U.S., and there was no TROP2 ADC approved for the same indication in China.

In the U.S., the 1L and 2L treatment options for advanced HR+/HER2- BC include various endocrine therapy regimens, such as an AI in combination with a CDK4/6 inhibitor and a SERD with or without a CDK4/6 inhibitor, and combination regimens with an endocrine therapy in combination with either a PI3K inhibitor or a mammalian target of rapamycin inhibitor for patients with PIK3CA mutations. The treatment paradigm in China is similar to that of the U.S. with an additional 2L option containing an AI plus chidamide, an epigenetic modulator.

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It is estimated that 40-50% of advanced HR+/HER2- BC patients are resistant to endocrine therapy, who have limited effective treatment options available, leaving a significant unmet need for effective non-endocrine therapy-based treatment.

NSCLC

Lung Cancer (LC) is the second most common cancer and the leading cause of cancer death worldwide. NSCLC is the most common subtype of LC and represents over 85% of all LC cases globally. Approximately 55% of patients with NSCLC have advanced disease at diagnosis. Advanced NSCLC patients have a five-year survival rate of about 8% in the U.S. and less than 5% in China. TROP2 overexpression is reported in about 64% to 75% of patients with NSCLC.

Incidence

The global incidence of NSCLC increased from 1.7 million in 2017 to 2.0 million in 2022 and is expected to grow to about 2.5 million in 2030. In China, the incidence of NSCLC grew from 714.2 thousand in 2017 to 836.8 thousand in 2022 and is anticipated to grow to 1.1 million in 2030.

Treatment Paradigm

The treatment paradigm of advanced NSCLC in the U.S. and China can be broadly classified based on the presence or absence of driver mutations. As of the Latest Practicable Date, there were no TROP2 ADCs approved for NSCLC worldwide.

In the U.S., for driver mutation-positive advanced NSCLC, the 1L treatment options include tyrosine kinase inhibitor (TKI), a type of targeted therapy, directed against specific actionable driver mutations. For driver mutation-negative advanced NSCLC, the 1L+ treatment options include chemoimmunotherapy with or without anti-angiogenic mAb bevacizumab, dual immunotherapy with PD-1 and CTLA-4 inhibitors with or without chemotherapy, and PD-(L)1 inhibitor monotherapy (for PD-L1+ patients).

In China, for driver mutation-positive NSCLC, TKIs are usually considered in the 1L setting. For patients who have failed TKIs, platinum-based doublet chemotherapy with or without bevacizumab, single-agent chemotherapy, or PD-(L)1 inhibitor monotherapy is usually considered. For driver mutation-negative advanced NSCLC, the 1L treatment options include chemoimmunotherapy with or without bevacizumab, doublet chemotherapy with or without PD-(L)1 inhibitor, and monotherapy with a PD-(L)1 inhibitor (for PD-L1+ patients). In the 2L setting, PD-(L)1 inhibitor monotherapy, single-agent chemotherapy and multi-targeting TKI anlotinib (for patients who have failed two chemotherapy regimens) are recommended.

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Despite the available treatment options, the prognosis of advanced NSCLC patients remains poor. Although the recent addition of PD-(L)1 inhibitors to standard treatments has improved the survival of patients with driver mutation-negative advanced NSCLC, many patients remain unresponsive. Meanwhile, each TKI is only clinically relevant for a subset of advanced NSCLC patients with a specific driver mutation, with an ORR ranging from approximately 30.0-93.0%. Consequently, there is a significant unmet need for innovative treatments that are potentially effective for a broader patient population regardless of driver mutation status.

GC

GC is the sixth most common and the third most deadly cancer worldwide. The prognosis of GC patients is poor as GC is often diagnosed at an advanced stage. It is estimated that about 40-50% of GC patients have advanced disease at presentation. Advanced GC patients have a five-year survival rate of less than 10% in both the U.S. and China. TROP2 overexpression is reported in about 56% of GC patients.

Incidence

The global incidence of GC increased from 1.0 million in 2017 to 1.2 million in 2022 and is expected to grow to 1.4 million in 2030. China is one of the countries with the highest incidence of GC, accounting for approximately 43.3% of the world’s GC patients in 2022. The incidence of GC in China grew from 429.0 thousand in 2017 to 498.6 thousand in 2022 and is anticipated to grow to 619.6 thousand in 2030.

Treatment Paradigm

The standard treatments of advanced GC in the U.S. and China primarily comprise chemotherapy, targeted therapy such as HER2-directed drugs and anti-angiogenic drugs, and PD-1 inhibitors. As of the Latest Practicable Date, there were no TROP2 ADCs approved for GC worldwide.

In the U.S., the 1L treatment options involve combination therapy regimens, including doublet chemotherapy plus HER2 mAb trastuzumab with or without PD-1 inhibitor for advanced HER2+ GC and doublet chemotherapy with PD-1 inhibitor for advanced HER2– GC. Treatments in the 2L+ setting include chemotherapy with or without anti-angiogenic mAb ramucirumab, single-agent chemotherapy and HER2 ADC Enhertu (for HER2+ GC), with combination chemotherapy trifluridine/tipiracil as a 3L+ treatment.

In China, the 1L treatment options involve combination therapy regimens that involve trastuzumab in combination with different chemotherapy for advanced HER2+ GC, doublet or triplet chemotherapy for advanced HER2– GC, and chemoimmunotherapy or PD-1 inhibitor monotherapy for PD-L1+ patients. The 2L treatment options include single-agent chemotherapy, trastuzumab combined with chemotherapy if no prior use of trastuzumab (for HER2+ GC), other chemotherapy regimens not previously used in the 1L and PD-1 inhibitor monotherapy for patients with MSI-high GC. The 3L+ treatment options include HER2 ADC Aidixi, apatinib (an anti-angiogenic TKI), PD-1 inhibitors and single-agent chemotherapy.

INDUSTRY OVERVIEW

There are limited targeted drugs in the existing treatment paradigm of advanced GC and immunotherapy has only modest efficacy. Given that TROP2 is overexpressed in the majority of both HER2+ and HER2- GC patients, ADCs targeting TROP2-expressing tumor cells represent a promising therapeutic strategy to treat a broad GC patient population regardless of HER2 status.

OC

OC is the third most common and the fifth deadliest cancer of the female reproductive system worldwide. About 70% of patients with OC have advanced disease at diagnosis. Advanced OC patients have a five-year survival rate of about 30% in the U.S. and around 30% to 40% in China. TROP2 overexpression is reported in about 59% of OC patients.

Incidence

The global incidence of OC increased from 289.3 thousand in 2017 to 326.4 thousand in 2022 and is expected to reach 379.9 thousand in 2030. The incidence of OC in China grew from 52.0 thousand in 2017 to 57.0 thousand in 2022 and is anticipated to reach 62.4 thousand in 2030.

Treatment Paradigm

Chemotherapy represents the mainstay of standard treatments for advanced OC in the U.S. and China. As of the Latest Practicable Date, there were no ADCs approved for OC worldwide.

The 1L treatments of advanced OC in the U.S. and China primarily involves debulking surgery with various regimens of platinum doublet chemotherapy with or without anti-angiogenic mAb bevacizumab. Patients with persistent disease or progression during 1L treatment are treated with 2L approaches depending on whether they are platinum-sensitive, i.e., OC that recurs more than six months after completing 1L platinum-based chemotherapy, or platinum-resistant, i.e., OC that recurs less than six months after completing 1L platinum-based chemotherapy. For platinum-sensitive OC, platinum doublet chemotherapy, bevacizumab and PARP inhibitors (for patients with deleterious BRCA mutations) are available as the 2L treatment options. For platinum-resistant OC, non-platinum chemotherapy, bevacizumab and PARP inhibitors (for patients with deleterious BRCA mutations) are available as the 2L options. PD-1 inhibitors may be considered for patients with certain immunotherapy biomarkers who have no satisfactory alternative treatment options.

Despite standard treatments, the prognosis of patients with advanced OC remains poor. Given that TROP2 is overexpressed in the majority of OC patients, TROP2 ADCs targeting TROP2-expressing tumor cells represent a promising therapeutic strategy.

INDUSTRY OVERVIEW

Competitive Landscape of the Global TROP2 ADCs Market

As of the Latest Practicable Date, Gilead Sciences’ Trodelvy was the only approved TROP2 ADC in the U.S., indicated for advanced TNBC, advanced UC and HR+/HER2- BC, and was the only TROP2 ADC approved by the NMPA for advanced TNBC. As of the same date, there were three TROP2 ADC candidates in phase 2 or beyond globally, including SKB264, Trodelvy (under the drug code of IMMU-132) and DS-1062. The following table illustrates the global competitive landscape of TROP2 ADCs.

Marketed TROP2 ADC Globally

Brand name (Generic name)	Company	Indication	FDA/NMPA approval date	Treatment line	Annual cost (in thousands)	Mono-/Combo-therapy	Country/region	2023 NRDL status	2022 revenue ⁽⁵⁾ (USD in millions)	2022 Market share ⁽⁵⁾
Trodelvy (Sacituzumab govitecan)	Gilead Sciences	Unresectable locally advanced or metastatic TNBC	Apr 2020	3L+	US\$372.7 ⁽¹⁾	Mono	U.S.	N/A	680 ⁽⁴⁾	100%
		Locally advanced or metastatic UC	Apr 2021	2L						
		HR+/HER2- BC	Feb 2023	3L+						
		Locally advanced unresectable or metastatic TNBC	Jun 2022	3L+	N/A ⁽²⁾	Mono	China	No		

Notes:

- (1) Assuming the average weight of patients is 80 kg and the duration of treatment is 52 weeks; based on market price in 2023.
- (2) Not yet priced in China.
- (3) According to the disclosure in 2022 annual report.
- (4) Global revenue.
- (5) In the global TROP 2 ADC market.

Source: FDA, NMPA, drug label, drug.com, Frost & Sullivan

In 2022, the global revenue of Trodelvy was USD680 million, and it was the only marketed TROP2 ADC globally as of the Latest Practicable Date.

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TROP2 ADC Candidates under Clinical Development Globally (phase 2 or beyond)⁽³⁾

Drug code (Generic name)	Company ⁽¹⁾	Indication	Clinical stage	First posted date	Mono-/Combo-therapy	Country/region
SKB264	Our Group/MSD	Advanced TNBC	Phase 3	Apr 2022	Mono	China
		TNBC	Phase 2	May 2022	Combo with or without A167	China
		Advanced EGFR-wild type and EGFR-mutant NSCLC (TKI failure)	Phase 2	Jul 2022	Combo with A167 with or without platinum-based chemotherapy	China
		EGFR-mutant NSCLC, NPC (PD-(L)1 relapsed or refractory)	Phase 2	Nov 2022	Mono	China
		Advanced solid tumors (RM-CC, advanced UC, recurrent and metastatic OC, advanced CRPC)	Phase 2	Dec 2022	Combo with Keytruda	China and U.S.
		Advanced EGFR-wild type and EGFR-mutant NSCLC	Phase 2	Mar 2023	Combo with Keytruda, osimertinib and chemotherapy	China
IMMU-132 (Sacituzumab govitecan)	Gilead Sciences	HR+/HER2- BC ⁽²⁾	Phase 3	Jan 2021	Mono	China
		UC ⁽²⁾	Phase 3	Jun 2021	Mono	China
		NSCLC	Phase 3	Nov 2022	Combo with Keytruda	U.S.
		PC	Phase 2	Oct 2018	Mono	U.S.
		EC	Phase 2	Jan 2020	Mono	U.S.
		Solid tumor	Phase 2	Nov 2021	Mono	China
		Muscle-invasive Bladder Carcinoma, Stage II and IIIA Bladder Cancer AJCC v8	Phase 2	Oct 2022	Mono	U.S.
		Cervical cancer	Phase 2	May 2023	Mono	U.S.
DS-1062 (Dato-DXd)	Daiichi Sankyo/AstraZeneca	NSCLC	Phase 3	Dec 2020	Mono	Australia, China, EU, Japan, United Kingdom, U.S. etc.
		HR+/HER2- BC	Phase 3	Nov 2021	Mono	China, EU, Japan, United Kingdom, U.S. etc.
		TNBC	Phase 3	May 2022	Mono	China, EU, Japan, United Kingdom, U.S. etc.
		TNBC	Phase 3	Nov 2022	Combo with durvalumab	EU, China, United Kingdom, U.S. etc.
		Advanced/metastatic NSCLC	Phase 3	Jan 2023	Combo with Keytruda, ± chemotherapy	China
		Locally advanced or metastatic NSCLC	Phase 3	Mar 2023	Combo with durvalumab and chemotherapy	China
Advanced/metastatic solid tumor (EC, GC, metastatic castration-resistant PC, OC, CRC)	Phase 2	Aug 2022	Combo with durvalumab/nivolumab/bevacizumab/chemotherapy	China, EU, Japan, United Kingdom, U.S. etc.		

Notes:

- (1) Only companies with drug right are listed.
- (2) IMMU-132 was not yet approved for UC or HR+/HER2- BC in China as of the Latest Practicable Date.
- (3) From CDE and clinicaltrials.gov.

Source: ClinicalTrials, CDE, Frost & Sullivan

For a competitive advantages analysis of TROP2 ADCs, see “Business – Our Pipeline – Oncology Franchise – ADCs – SKB264 – Competitive Advantages.”

INDUSTRY OVERVIEW

CHINA’S HER2 ADC MARKET

Overview

HER2 is a cell surface receptor that is lowly expressed in various normal tissues, but its aberrant activation through overexpression in tumor cells promote their aberrant growth and survival, thus driving the development of various types of cancers including BC and GI cancers such as GC, CRC and esophageal cancer. As a result, HER2 has been a well-established cancer drug target with successful HER2-targeted therapies in different modalities, among which HER2 ADC represents one of the recent and clinically proven strategies.

Addressable Market Size of HER2 ADCs

The table below highlights the major cancers where HER2 is frequently overexpressed. Among them, advanced HER2+ BC, the lead indication of A166, is one of the major types of advanced HER2+ solid tumors. Apart from A166, there were two approved HER2 ADCs, Genentech’s Kadcyla and Daiichi Sankyo’s Enhertu, and eight HER2 ADCs in phase 2 or beyond, that target the same lead indication as A166 in China as of the Latest Practicable Date. See “– China’s HER2 ADC Market – Competitive Landscape of HER2 ADCs” for further details.

Indication	Overexpression ⁽¹⁾
BC	15-30%
GC	10-30%
CRC	3-5%
OC	20-30%
Esophageal Cancer	7-22%
EC	18-80%
NSCLC	13-20%

Note:

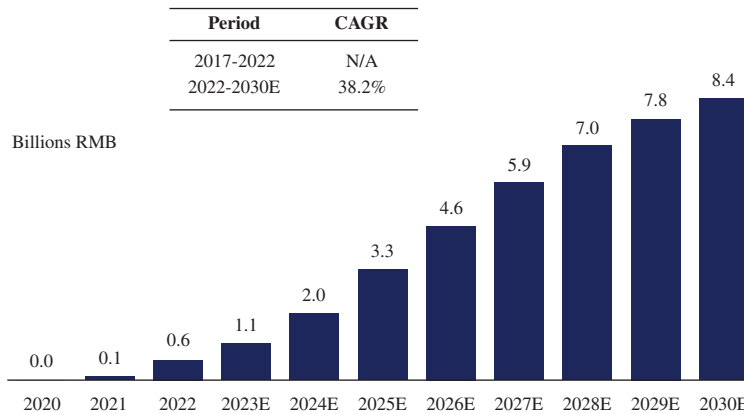
(1) “Overexpression” refers to the proportion of patients with HER2 overexpression for a given indication.

Sources: Literature Review, Frost & Sullivan

INDUSTRY OVERVIEW

As shown in the charts below, the HER2 ADC market in China was RMB0.6 billion in 2022 and is forecasted to increase to RMB8.4 billion in 2030, representing a CAGR of 38.2% from 2022.

China HER2 ADCs Market Size, 2020-2030E



Sources: NMPA, annual report, MOHRSS, Frost & Sullivan

HER2+ BC

HER2+ BC is a major subtype of BC, representing approximately 15-30% of total BC cases. It is characterized by HER2 overexpression, measured by immunohistochemistry and fluorescence in situ hybridization methods. Compared with HER2– BC, HER2+ BC tends to grow faster and be more aggressive, and patients with HER2+ BC have a worse prognosis. About 20-25% of HER2+ BC patients present with advanced disease at the time of diagnosis, and 20% of early-stage patients eventually develop advanced disease. Patients with advanced HER2+ BC have a five-year survival rate of less than 20% in China.

Incidence

The incidence of HER2+ BC in China increased from 80.1 thousand in 2017 to 86.6 thousand in 2022 and is expected to reach 94.1 thousand in 2030.

Treatment Paradigm

The standard treatments of advanced HER2+ BC in China primarily comprise chemotherapy, targeted therapy such as HER2 mAbs, TKIs and HER2 ADC. As of the Latest Practicable Date, Kadcylla and Enhertu were the only HER2 ADCs approved for advanced HER2+ BC in China.

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For advanced HER2+ BC patients eligible for HER2 mAb trastuzumab treatment, 1L treatment options include taxane-based chemotherapy in combination with trastuzumab and pertuzumab, a HER2 dimerization inhibitor, or doublet chemotherapy with trastuzumab. 2L options include combination chemotherapy with a HER2 mAb, or EGFR/HER2 TKI pyrotinib in combination with chemotherapy capecitabine, with triple-combination therapy involving a HER2 mAb pertuzumab or TKIs, and other chemotherapy as the 3L treatment. For advanced HER2+ BC patients who previously failed trastuzumab, pyrotinib in combination with capecitabine is recommended as the 1L treatment. 2L options include HER2 ADC Kadcyla monotherapy and combination therapy with capecitabine and EGFR/HER2 TKI lapatinib. 3L options include EGFR/HER2/HER4 TKI neratinib in combination with capecitabine, pyrotinib monotherapy and other TKI/HER2 mAb-chemotherapy combinations. HER2 ADC Enhertu monotherapy is also approved for patients with unresectable or metastatic HER2+ BC who have received one or more prior anti-HER2-based regimens.

Despite the advances in anti-HER2 therapies, a significant number of patients remain unresponsive or experience treatment resistance and/or significant side effects. Kadcyla and Enhertu, for example, carry notable safety concerns, including black box warning issued by the FDA for hepatic, cardiac and embryo-fetal toxicities for Kadcyla, and interstitial lung disease and embryo-fetal toxicity for Enhertu. These limitations highlight a significant unmet need for safer treatments that can prolong the survival for relapsed or refractory patients.

HER2+ GC

HER2+ GC accounts for about 10-30% of total GC cases. It is characterized by HER2 overexpression, a major actionable oncogenic alteration in GC. About 50% of HER2+ GC patients present with advanced disease at the time of diagnosis. Patients with advanced HER2+ GC have a median OS of 13.8 months in China.

Incidence

The incidence of HER2+ GC in China increased from 102.5 thousand in 2017 to 119.2 thousand in 2022 and is expected to reach 148.1 thousand in 2030.

Treatment Paradigm

The standard treatments of advanced HER2+ GC in China primarily comprise chemotherapy and HER2-directed drugs including HER2 mAb trastuzumab and HER2 ADC Aidixi. As of the Latest Practicable Date, Aidixi was the only HER2 ADC approved for advanced HER2+ GC in China. For details of the standard treatments for advanced HER2+ GC in China, see “– Global and China’s TROP2 ADC Markets – Addressable Market Size of TROP2 ADCs – GC – Treatment Paradigm.”

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Although the use of trastuzumab in combination with chemotherapy in early-line HER2+ GC patients generally improves patient outcome compared with conventional chemotherapy, a significant portion of patients do not respond to trastuzumab and the majority of patients who initially benefit from trastuzumab develop drug resistance. These patients have limited effective 2L+ treatment options, with Aidixi being the only HER2-directed drug available in the 3L+ setting. This underscores a significant unmet need for novel HER2-directed drugs to overcome trastuzumab resistance and widen the treatment options for 2L+ HER2+ GC patients.

HER2+ CRC

CRC is the third most prevalent cancer and a leading cause of cancer mortality in China. HER2+ CRC represents about 3% to 5% of total CRC cases. HER2 overexpression is associated with a more advanced disease stage of CRC. About 36% of patients with HER2+ CRC have advanced disease at diagnosis, and patients with advanced HER2+ CRC have a five-year survival rate of 10% in China.

Incidence

The incidence of HER2+ CRC in China increased from 16.5 thousand in 2017 to 19.3 thousand in 2022 and is expected to reach 24.1 thousand in 2030.

Treatment Paradigm

The treatment paradigm of advanced HER2+ CRC in China largely comprises non-HER2-directed drugs. As of the Latest Practicable Date, there were no ADCs approved for HER2+ CRC in China.

The 1L and 2L treatments for advanced HER2+ CRC largely follow those recommended for advanced CRC with wild-type RAS/BRAF. For patients with certain immunotherapy biomarkers, PD-1 inhibitor is recommended as the 1L treatment. For patients with wild-type RAS/BRAF who can withstand higher treatment toxicity, the 1L treatment includes (i) doublet chemotherapy (5-fluorouracil/leucovorin plus either oxaliplatin (FOLFOX) or irinotecan (FOLFIRI)) with or without EGFR mAb cetuximab (for left-sided tumors), or anti-angiogenic mAb bevacizumab (for right-sided tumors), and (ii) doublet chemotherapy (capecitabine plus oxaliplatin (CAPEOX)). For patients who cannot withstand higher treatment toxicity, chemotherapy 5-fluorouracil with or without bevacizumab is recommended as the 1L treatment. For patients who received oxaliplatin in the 1L treatment, FOLFIRI with or without cetuximab or bevacizumab is recommended as the 2L treatment. For patients who received irinotecan in the 1L treatment, 2L treatment options include FOLFOX with or without cetuximab or bevacizumab, and CAPEOX with or without bevacizumab.

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As of the Latest Practicable Date, there were no HER2-directed drugs approved by the NMPA for advanced HER2+ CRC. The response rates of advanced HER2+ CRC patients to current non-HER2-directed standard treatments are only between 10.0% to 35.3%, leaving many patients with limited clinical benefit and highlighting the significant unmet need for novel HER2-directed drugs to improve the survival of advanced HER2+ CRC patients. Recent clinical trial results of HER2-directed therapies have demonstrated promising efficacy and favorable safety in HER2+ CRC patients, thus underscoring the potential of HER2-directed therapies for HER2+ CRC.

Competitive Landscape of HER2 ADCs

As of the Latest Practicable Date, Genentech’s Kadcyla, Remegen’s Aidixi and Daiichi Sankyo’s Enhertu were the only three HER2 ADCs approved in China. Kadcyla is indicated for early-stage HER2+ BC and advanced HER2+ BC, Aidixi is indicated for advanced HER2+ GC and advanced HER2+ UC, while Enhertu is indicated for advanced HER2+ BC. As of the same date, there were nine HER2 ADC candidates targeting BC in phase 2 or beyond in China. The following tables illustrate the competitive landscape of HER2 ADCs in China.

Marketed HER2 ADCs in China

Brand name (Generic name)	Company	Indication	NMPA approval date	Treatment line	Annual cost ⁽¹⁾ (RMB in thousands)	2023 NRDL status	2022 Revenue ⁽²⁾ (RMB in millions)	2022 Market share ⁽³⁾
Kadcyla (Ado-trastuzumab emtansine)	Genentech (Roche)	HER2+ early BC	Jan 2020	Adjuvant (post-surgery)	120.0	Yes	N/A	34.4%
		HER2+ unresectable locally advanced/metastatic BC	Jun 2021	2L				
Aidixi (Disitamab vedotin)	RemeGen	HER2 overexpression locally advanced/metastatic GC (including GEJ adenocarcinoma)	Jun 2021	3L	247.0	Yes	N/A	65.6%
		HER2+ locally advanced/metastatic UC	Jan 2022	2L	197.6			
Enhertu (Trastuzumab deruxtecan)	Daiichi Sankyo/ AstraZeneca	HER2+ unresectable or metastatic BC	Feb 2023	2L+	N/A	No	N/A	N/A

Notes:

- (1) Assuming the average weight of patients is 60 kg and the duration of treatment is 52 weeks; based on market price in 2023.
- (2) According to the disclosure in 2022 annual report.
- (3) In China’s HER2 ADC market.

Sources: NMPA, drug label, NRDL, Frost & Sullivan

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In 2022, according to Frost & Sullivan, Kadcylya and Aidixi had a market share of 34.4% and 65.6%, respectively, among marketed HER2 ADC drugs in China. In the same year, Enhertu was not yet approved.

HER2 ADC Candidates for BC under Clinical Development in China (phase 2 or beyond)

Drug code (Generic name)	Company ⁽¹⁾	Indication	Clinical stage	First posted date
A166	Our Group	Advanced HER2+ BC	NDA registration	Aug 2021
Aidixi (Disitamab Vedotin)	Remegen	HER2+ locally advanced or metastatic BC, HER2+ advanced BC with liver metastasis	Phase 3	May 2018
		HER2 low expression, locally advanced or metastatic BC	Phase 3	May 2020
DS-8201 (Trastuzumab deruxtecan)	Daiichi Sankyo/AstraZeneca	HER2 low expression, HR+ advanced or metastatic BC	Phase 3	Nov 2020
		high risk of HER2+ residual invasive BC	Phase 3	Mar 2021
		HER2+ early BC	Phase 3	Mar 2022
SHR-A1811	Jiangsu Hengrui Medicine	Metastatic BC	Phase 3	Jun 2022
		HER2 low expression recurrent or metastatic BC	Phase 3	Apr 2023
FS-1502	Fosun Pharmaceutical	HER2+ unresectable locally advanced or metastatic BC	Phase 3	Feb 2023
ARX788	Zhejiang Medicine	HER2+ BC	Phase 2/3	Aug 2020
MRG002	Miracogen	HER2+ unresectable locally advanced or metastatic BC	Phase 2/3	May 2021
		HER2 low expression locally advanced or metastatic BC	Phase 2	Feb 2021
		HER2+ BC with liver metastasis	Phase 2	Jan 2022
DX126-262	DAC Biotech Company	HER2+ unresectable locally advanced, or recurrent metastatic BC	Phase 2	Aug 2021
DP303C	CSPC Pharmaceutical Group	HER2+ unresectable locally advanced, recurrent or metastatic BC	Phase 2	Apr 2022

Note:

(1) Only companies with drug right are listed.

Sources: CDE, Frost & Sullivan

For a competitive advantages analysis of HER2 ADCs, see “Business – Our Pipeline – Oncology Franchise – ADCs – A166 – Competitive Advantages.”

INDUSTRY OVERVIEW

GLOBAL CLDN18.2 ADC MARKET

Overview

CLDN18.2 is a cell junction protein whose expression is strictly confined to the gastric mucosa, or the innermost layer of the stomach wall, largely inaccessible to targeting antibodies under normal conditions. However, disruptions in cell junctions during cancer development expose CLDN18.2 epitopes on the surface of tumor cells, thus allowing CLDN18.2 to be specifically targeted. Besides GC, CLDN18.2 overexpression has been identified in various types of tumors derived from organs where CLDN18.2 is not normally expressed, such as pancreatic and esophageal cancers. The tumor-selective feature and distribution of CLDN18.2 across some of the most aggressive cancers make CLDN18.2 an attractive candidate for the development of targeted therapy, including novel treatment modalities such as ADCs.

Addressable Market Size of CLDN18.2 ADCs

The table below highlights the major cancers where CLDN18.2 is frequently overexpressed.

Indication	Overexpression ⁽¹⁾
PC	60-90%
GC	42-86%
Esophagus adenocarcinoma	30%
Mucinous cystadenoma of ovary	91%

Note:

(1) “Overexpression” refers to the proportion of patients with CLDN18.2 overexpression for a given indication.

Sources: Literature Review, Frost & Sullivan

As of the Latest Practicable Date, there were no CLDN18.2 ADCs approved worldwide. The CLDN18.2 ADC market is directly correlated to and can be estimated by the number of addressable patients with PC and GC, two cancer indications where CLDN18.2 ADCs were more clinically advanced, as of the Latest Practicable Date. Globally, the total addressable patient size of CLDN18.2 ADCs was 1.7 million in 2022 and is forecasted to reach 2.1 million in 2030.

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Competitive Landscape of CLDN18.2 ADCs

CLDN18.2 is a relatively new cancer drug target with no CLDN18.2-targeted drugs approved worldwide. As of the Latest Practicable Date, there were 13 CLDN18.2 ADC candidates under clinical development globally, most of which were in early clinical trial stages. The table below summarizes the competitive landscape of CLDN18.2 ADCs globally.

CLDN18.2 ADC Candidates under Clinical Development Globally

Drug code	Company ⁽¹⁾	Indication	Clinical stage	First posted date	Country/region
LM-302	LaNova Medicines	Advanced solid tumor	Phase 1/2	Dec 2021	China
	Turning Point Therapeutics			Aug 2021	U.S.
RC118-ADC	RemeGen	Advanced solid tumor	Phase 1/2	Jan 2022	China
		Unresectable/metastatic/locally advanced solid tumor	Phase 1	Aug 2021	Australia
SHR-A1904	Jiangsu Hengrui Medicine	Advanced solid tumors	Phase 1/2	Mar 2022	Australia, U.S.
		Advanced solid tumors	Phase 1	May 2021	China
		Advanced PC		Jun 2021	
SOT102	SOTIO Biotech	GC, PC, GEJ cancer	Phase 1/2	Sep 2022	Belgium, Czechia, France, Spain, U.S.
CMG901	Keymed Biosciences	Advanced solid tumor, GC, GEJ adenocarcinoma, PC	Phase 1	Mar 2021	China
SYSA1801	CSPC Pharmaceutical Group	Advanced solid tumor, GC, GEJ cancer, PC	Phase 1	Aug 2021	China
CPO102		PC, GC	Phase 1	Sep 2021	N/A
TORL-2-307-ADC	TORL Biotherapeutics	Advanced solid tumor, GC, PC, GEJ adenocarcinoma	Phase 1	Dec 2021	U.S.
SKB315	MSD	Advanced solid tumor	Phase 1	May 2022	China
IBI343	Innovent Biologics	Locally advanced unresectable or metastatic solid tumors	Phase 1	Jul 2022	Australia
JS107	Shanghai Junshi Bioscience	Advanced solid tumor	Phase 1	Aug 2022	China
		Advanced PC		Dec 2022	
ATG-022	Antengene Biologics	Advanced or metastatic solid tumors	Phase 1	Feb 2023	Australia, China
TQB2103	Chia Tai Tianqing Pharmaceutical	Advanced malignant neoplasm	Phase 1	May 2023	China

Note:

(1) Only companies with drug right are listed.

Sources: ClinicalTrials, Frost & Sullivan

For a competitive advantages analysis of CLDN18.2 ADCs, see “Business – Our Pipeline – Oncology Franchise – ADCs – SKB315 – Competitive Advantages.”

INDUSTRY OVERVIEW

CHINA’S PD-(L)1 MAB MARKET

Overview of Immune Checkpoint Inhibitors

Cancer immunotherapy has become an integral part of cancer treatment, bringing unprecedented survival benefits to patients with once rapidly fatal cancers by engaging patients’ own immune system to fight cancers effectively.

Among the different categories of cancer immunotherapy, immune checkpoint inhibitors represent a core immunotherapeutic approach. Using targeting antibodies to block immune checkpoint proteins, which are negative regulators of T cell activation, immune checkpoint inhibitors counteract immunosuppression exerted by tumor cells and their microenvironment to unleash a powerful antitumor immune response. PD-1, its ligand PD-L1, and CTLA-4 are widely recognized as three of the most clinically validated checkpoint molecules. As of the Latest Practicable Date, all immune checkpoint inhibitors approved globally and in China were in the form of mAbs, except for Kaitanni, a PD-(L)1/CTLA-4 bsAb approved in China. As of the same date, five PD-1 mAbs, three PD-L1 mAbs and two CTLA-4 mAbs were approved by the FDA, while ten PD-1 mAbs, five PD-L1 mAbs and one CTLA-4 mAb were approved in China.

China’s PD-(L)1 MAb Market

Overview

PD-1 and its ligand PD-L1 are major immune checkpoint proteins responsible for controlling the continued activation and proliferation of activated T cell effectors. The interaction of PD-1 with PD-L1 can induce T cell exhaustion, a dysfunctional T cell state, to suppress the activity of activated T cells. This immunosuppressive function of PD-(L)1 signaling is often exploited by tumor cells to evade immune attack. Given that PD-1 is widely expressed in immune cells and PD-L1 is overexpressed in many cancers, PD-(L)1 blockade via PD-(L)1 mAbs has clinically proven to be successful in reinvigorating antitumor immune response across a broad range of cancer indications. PD-(L)1 blockade is also associated with a lower incidence of serious AEs compared to chemotherapy and a lower rate of immune-related AEs compared to CTLA-4 blockade. For details of the mechanism of action of PD-(L)1 mAbs, see “Business – Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A167 – Mechanism of Action.”

Addressable Market Size of PD-(L)1 MABs

The PD-(L)1 mAb market in China has grown rapidly since the NMPA approval of the first PD-1 mAb in 2018 and the first PD-L1 mAb in 2019, as PD-(L)1 mAbs have been incorporated into the 1L and 2L treatments for many cancer indications. Expanding cancer indications and the increasing use of combination therapies that couple PD-(L)1 mAbs with other therapeutic agents, such as ADCs, are expected to further expand the PD-(L)1 mAb market in the near future. China’s PD-(L)1 mAb market was RMB18.3 billion in 2022 and is anticipated to reach RMB48.3 billion in 2030 at a CAGR of 12.9% from 2022.

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TNBC

For details, see “– Global and China’s Trop2 ADC Markets – Addressable Market Size of TROP2 ADCs – TNBC.”

NSCLC

For details, see “– Global and China’s Trop2 ADC Markets – Addressable Market Size of TROP2 ADCs – NSCLC.”

NPC

NPC is a type of head and neck cancer that develops in the nasopharynx, an area in the upper part of the throat that connects to the nasal cavities. It has a higher prevalence in China, especially Southern China, than in western countries. RM-NPC represents approximately 35% of total NPC, and patients with RM-NPC have a five-year survival rate of 10-20% in China.

Incidence

The incidence of NPC in China grew from about 59.5 thousand in 2017 to 64.0 thousand in 2022 and is expected to reach 69.1 thousand in 2030.

Treatment Paradigm

For recurrent NPC that cannot be removed by surgery, repeat radiotherapy is the recommended 1L treatment, while the 2L treatment guideline follows that of metastatic NPC. For metastatic NPC, the 1L treatment is combination chemotherapy with or without a PD-1 mAb. The 2L+ treatment options include single-agent chemotherapy and PD-1 mAb monotherapy.

The current standard of care only offers modest therapeutic benefits, with the effective rates of PD-1 mAb monotherapy ranging from approximately 20% to 30%. Given that PD-L1 is expressed in about 89% to 95% of NPC tumors, PD-L1 blockade by PD-L1 mAb is a promising therapeutic strategy to expand the currently limited treatment options for RM-NPC.

Competitive Landscape of PD-(L)1 MAbs Combination Therapies With TROP2 ADCs

As of the Latest Practicable Date, there were five PD-(L)1 mAbs combination therapies with TROP2 ADC in phase 2 or beyond in China.

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PD-(L)1 MAbs Combination Therapies With TROP2 ADC Candidates under Clinical Development in China (phase 2 or beyond)

Drug code (Generic name)	Company ⁽¹⁾	Indication	Clinical stage	First posted date
A167+SKB264	Our Group	Advanced NSCLC	Phase 2	May 2022
		Advanced TNBC	Phase 2	Jul 2022
Keytruda+SKB264	MSD+Our Group	Solid tumor (r/r CC, LA/metastatic UC, metastatic CRPC, recurrent OC)	Phase 2	Dec 2022
Keytruda+SKB264 +osimertinib+chemotherapy		Advanced EGFR-wild type and EGFR-mutant NSCLC	Phase 2	Mar 2023
Keytruda+DS-1062	MSD+Daiichi Sankyo	Advanced or metastatic NSCLC	Phase 3	Jan 2023
Durvalumab+DS-1062	AstraZeneca+Daiichi Sankyo	Advanced or metastatic solid tumor	Phase 2	Nov 2022
		Locally advanced or metastatic NSCLC	Phase 3	Mar 2023

Note:

(1) Only companies with drug right are listed.

Sources: CDE, Frost & Sullivan

Competitive Landscape of PD-(L)1 MAbs for RM-NPC

As of the Latest Practicable Date, there were three approved PD-1 mAbs and no approved PD-L1 mAbs for treating RM-NPC in China. As of the same date, there were one PD-1 mAb and one PD-L1 mAb at NDA registration stage for RM-NPC in China. The table below sets forth the competitive landscape of PD-(L)1 mAbs for RM-NPC in China.

Marketed PD-1 MAbs for RM-NPC in China

Brand name (Generic name)	Company	Indication	NMPA approval date	Treatment line	Annual cost ⁽¹⁾ (RMB in thousands)	2023 NRDL status	2022 Revenue ⁽²⁾ (RMB in millions)	2022 Market share ⁽³⁾
Tuoyi (Toripalimab)	Shanghai Junshi Biosciences	RM-NPC	Feb 2021	3L+	37.3	Yes	736	4.4%
		Locally RM-NPC	Nov 2021	1L	33.2	No		
Airuika (Camrelizumab)	Jiangsu Hengrui Medicine	Advanced NPC	Apr 2021	3L+	67.0	Yes	3,701.4	20.4%
		Locally RM-NPC	Jun 2021	1L		Yes		
Baizean (Tislelizumab)	Beigene	RM-NPC	Jun 2022	1L	47.8	Yes	2,845.9	16.9%

Notes:

(1) Assuming the average weight of patients is 60 kg and the duration of treatment is 52 weeks; based on market price in 2023.

(2) According to the disclosure in 2022 annual report.

(3) In China's PD-(L)1 mAb market

Source: NMPA, drug label, NRDL, Frost & Sullivan

INDUSTRY OVERVIEW

PD-(L)1 MAb Candidates under Clinical Development for RM-NPC in China (phase 3 or beyond)

Drug code (Generic name)	Company ⁽¹⁾	Indication	Mono/Combo Therapy	Clinical stage	First posted date
AKI05/Penpulimab	Akeso Biopharma	Metastatic NPC	Mono	NDA registration	May 2020
		RM-NPC	Combo with Chemotherapy	Phase 3	Jun 2021
A167	Our Group	RM-NPC	Mono	NDA registration	Nov 2021
		RM-NPC	Combo with Chemotherapy	Phase 3	Mar 2022

Note:

(1) Only companies with drug right are listed.

Sources: CDE, Frost & Sullivan

For a competitive advantages analysis of the PD-(L)1 mAbs for treating RM-NPC, see “Business – Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A167 – Competitive Advantages.”

CHINA’S EGFR MAB MARKET

Overview

EGFR is a cell surface receptor with key roles in multiple signaling pathways that promote cell proliferation and survival. Aberrant activation of EGFR, such as overexpression or mutation, is widely established as an oncogenic driver in a wide range of cancers, such as CRC, HNSCC and NSCLC. EGFR inhibition has thus become a major focus of targeted therapy with EGFR mAbs being one of the most clinically validated modalities. See “Business – Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A140 – Mechanism of Action” for details regarding the mechanism of action of EGFR mAbs.

In addition to being a promising monotherapy, combining EGFR mAbs with chemotherapy, radiotherapy or chemoradiotherapy has significantly improved patient survival in clinical trials compared to conventional treatments alone.

Addressable Market Size of EGFR mAbs

The EGFR mAb market in China grew from RMB0.8 billion in 2017 to RMB4.1 billion in 2022 at a CAGR of 37.3%. With the anticipated biosimilars market entry and new EGFR mAb launches, China’s EGFR mAb market is expected to reach RMB10.6 billion in 2030, representing a CAGR of 12.8% from 2022.

INDUSTRY OVERVIEW

RAS wild-type mCRC

CRC is the third most prevalent type of cancer in China. About 20% of patients with CRC have metastases at the time of diagnosis, and around 80% of patients with CRC develop metastatic disease. The overall five-year survival rate for mCRC is only around 10%. RAS wild-type mCRC, a major type of mCRC targetable by EGFR-directed therapies, represents approximately half of all mCRC cases.

Incidence

The incidence of RAS wild-type mCRC in China grew from 173.7 thousand in 2017 to 202.5 thousand in 2022 and is expected to reach 253.6 thousand in 2030.

Treatment Paradigm for RAS Wild-type mCRC

In China, the treatment paradigm for RAS wild-type mCRC primarily involves combination chemotherapy with cetuximab or anti-angiogenic mAb bevacizumab. For details regarding the standard treatments for RAS wild-type mCRC, see “– China’s HER2 ADC Market – Addressable Market Size of HER2 ADCs – HER2+ CRC – Treatment Paradigm.”

HNSCC

HNSCC is a group of cancers arising from mucosal surfaces of the mouth, nose and throat and accounts for more than 90% of head and neck cancer. Locally advanced HNSCC (LA-HNSCC) accounts for approximately 60% of all HNSCC cases, and RM-HNSCC accounts for approximately 50% of all HNSCC cases. The five-year survival rate of patients with LA-HNSCC and RM-HNSCC in China is 50% and 3.6%, respectively.

Incidence

The incidence of LA-HNSCC in China grew from about 72.4 thousand in 2017 to 80.5 thousand in 2022 and is expected to reach 91.9 thousand in 2030. The incidence of RM-HNSCC in China grew from about 60.3 thousand in 2017 to 67.1 thousand in 2022 and is expected to reach 76.6 thousand in 2030.

Treatment Paradigm

For LA-HNSCC, the current treatment paradigm in China consists of surgery, radiotherapy, platinum-based chemotherapy and targeted therapy. 1L treatment options include surgery with or without radiotherapy or radiochemotherapy, radiotherapy in combination with platinum-based chemotherapy, and induction chemotherapy followed by radiotherapy, with cetuximab in combination with radiotherapy available in the 2L setting.

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For RM-HNSCC, palliative platinum-based chemotherapy with or without targeted therapy is currently the mainstay of treatment for patients not suitable for surgery and radiotherapy. In China, PD-1 mAb monotherapy and doublet chemotherapy in combination with cetuximab represent the 1L treatment options, with PD-1 inhibitor nivolumab as monotherapy in the 2L setting.

Competitive Landscape of EGFR mAbs

As of the Latest Practicable Date, two EGFR mAbs, cetuximab and nimotuzumab, were approved in China.

Marketed EGFR MABs in China

Brand name (Generic name)	Company	Indication	NMPA approval date	Treatment line	Annual cost ⁽¹⁾ (RMB in thousands)	2023 NRDL status	2022 Revenue ⁽²⁾ (RMB in millions)	2022 Market share ⁽³⁾
Theraloc (Nimotuzumab)	Biotech Pharma	NPC	Jan 2008	1L	23.0	Yes	N/A	40.6%
Erbix (Cetuximab)	Eli Lilly and Company, Merck, BMS	RAS wild-type mCRC	Sep 2019	1L	137.8	Yes	N/A	59.4%
		RM-HNSCC	Mar 2020					
		LA-HNSCC	Jun 2022			Yes		

Notes:

- (1) Assuming the average weight of patients is 60 kg and the duration of treatment is 52 weeks; based on market price in 2023.
- (2) According to the disclosure in 2022 annual report.
- (3) In China’s EGFR mAb market.

Source: NMPA, drug label, NRDL, Frost & Sullivan

China’s clinical development landscape for EGFR mAbs is dominated by cetuximab biosimilars, mainly driven by superior market performance of cetuximab and expiration of patent protection for cetuximab in China in 2017, opening the door for biosimilars to enter the market. As of the Latest Practicable Date, no cetuximab biosimilars had been approved by the NMPA, and there were two cetuximab biosimilar candidates in phase 3 or beyond in China. The following table sets forth the competitive landscape for cetuximab biosimilars in China.

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Cetuximab Biosimilar Candidates under Clinical Development in China (phase 3 or beyond)

Drug code	Company ⁽¹⁾	Indication	Clinical stage	First posted date
APZ001	ANNPO Biotechnology	mCRC	Phase 3	Oct 2019
A140	Our Group	RAS wild-type mCRC	Phase 3	Dec 2020

Note:

(1) Only companies with drug right are listed.

Sources: CDE, Frost & Sullivan

For a competitive advantages analysis of cetuximab biosimilar candidates, see “Business – Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A140 – Competitive Advantages.”

CHINA’S SELECTIVE RET INHIBITOR MARKET

Overview

Rearranged during transfection (RET) gene is a cell surface signaling receptor that regulates cell differentiation, growth and migration. Genetic alterations of RET, such as mutations and fusions, have been implicated in the pathogenesis of approximately 2% of human cancers (“RET+ cancers”), including about 1-2% of NSCLC and 33% of thyroid cancer (TC). Selectively inhibiting RET has thus been a promising approach to treat RET+ cancers. See “Business – Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A400 – Mechanism of Action” for details of the mechanism of action of selective RET inhibitors.

Addressable Market Size of Selective RET Inhibitors

Following the NMPA approval of the first selective RET inhibitor in 2021, the selective RET inhibitor market in China is expected to increase from RMB0.3 billion in 2022 to RMB1.8 billion in 2030 at a CAGR of 22.9% from 2022.

RET+ NSCLC

RET+ NSCLC amounts to approximately 1% to 2% of total NSCLC cases. See “– Global and China’s TROP2 ADC markets – Addressable Market Size of TROP2 ADCs – NSCLC” for details regarding NSCLC.

INDUSTRY OVERVIEW

Incidence

The incidence of RET+ NSCLC in China grew from 13.6 thousand in 2017 to 15.9 thousand in 2022 and is expected to reach 20.0 thousand in 2030.

Treatment Paradigm

In China, the treatment paradigm of advanced RET+ NSCLC largely follows treatment guidelines recommended for driver mutation-negative advanced NSCLC, which involves chemoimmunotherapy with or without anti-angiogenic mAb bevacizumab and monotherapy with PD-L1 inhibitor for PD-L1+ patients, with the addition of RET inhibitor Retevmo as another 1L option. The 2L+ treatment options include single-agent chemotherapy, doublet chemotherapy with or without bevacizumab, PD-1 inhibitor monotherapy, and RET inhibitors Gavreto and Retevmo (for patients who have not received 1L targeted therapy).

Standard non-RET inhibitor therapies provide limited benefit for RET+ NSCLC patients, and the therapy outcomes in these patients are generally poor. Although two selective RET inhibitors, Gavreto and Retevmo, have been added to the standard treatments, their therapeutic benefits are limited by acquired resistance partially due to RET mutations developed during the treatment course, as well as safety issues such as hypertension and hematological toxicity, necessitating the development of novel selective RET inhibitors with improved safety and better efficacy against drug resistant mutations.

RET+ MTC

TC is a type of cancer that develops in the thyroid gland. It has been among the fastest growing cancers in China in recent years. Medullary TC (MTC) is one of the subtypes of TC, accounting for about 3% of total TC cases. RET mutations represent a major driver of MTC. They occur in about 90% of MTCs and are associated with advanced disease and a poor clinical outcome.

Incidence

The incidence of RET+ MTC in China grew from 5.6 thousand in 2017 to 6.2 thousand in 2022 and is expected to reach 7.4 thousand in 2030.

Treatment Paradigm

The treatment paradigm of advanced unresectable RET+ MTC in China includes selective RET inhibitor Gavreto in the 1L setting and selective RET inhibitor Retevmo in the 2L setting. Despite the initially promising treatment responses to Gavreto and Retevmo, many patients eventually progress as their tumors acquire RET resistant mutations to these two selective RET inhibitors. Moreover, Retevmo and Gavreto are associated with safety issues such as hypertension and hematological toxicity that limit their clinical use. This indicates a significant unmet need for novel selective RET inhibitors with improved safety and better efficacy against drug resistant mutations.

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Competitive Landscape of Selective RET Inhibitors

As of the Latest Practicable Date, Gavreto and Retevmo were the only two selective RET inhibitors approved in China, and there were six selective RET inhibitor candidates in phase 1/2 or beyond in China as of the same date.

Marketed Selective RET Inhibitors in China

Brand name (Generic name)	Company	Indication	NMPA approval date	Treatment line	Annual cost ⁽¹⁾ (RMB in thousands)	2023 NRDL status	2022 Revenue ⁽²⁾ (RMB in millions)	2022 Market share ⁽³⁾
Gavreto (Pralsetinib)	CStone Pharmaceuticals	Metastatic RET fusion-positive NSCLC	Mar 2021	2L	728.0	No	N/A	100%
		Advanced or metastatic RET fusion-positive TC	Mar 2022	1L				
		Advanced or metastatic RET-mutant MTC						
Retevmo (Selpercatinib)	Eli Lilly and Company	Metastatic RET fusion-positive NSCLC	Oct 2022	1L	1,855.9	No	N/A	N/A
		Adults with advanced or metastatic RET mutated MTC						
		Advanced or metastatic RET fusion positive TC						

Notes:

- (1) Assuming the average weight of patients is 60 kg and the duration of treatment is 52 weeks; based on market price in 2023.
- (2) According to the disclosure in 2022 annual report.
- (3) In China’s selective RET inhibitor market.

Source: NMPA, drug label, NRDL, Frost & Sullivan

INDUSTRY OVERVIEW

Selective RET Inhibitor Candidates under Clinical Development in China (phase 1/2 or beyond)

Drug code (Generic name)	Company ⁽¹⁾	Indication	Clinical stage	First posted date
Loxo-292 (Selpercatinib)	Eli Lilly	RET fusion solid tumor, RET mutant MTC and other RET active tumor	Phase 2	Jan 2020
BYS10	Baiyunshan Pharmaceutical	Adult advanced solid tumor	Phase 1/2	Apr 2022
Blu-667	CStone Pharmaceuticals	Adult MTC, RET fusion NSCLC and other RET mutant advanced solid tumor	Phase 1/2	May 2019
A400	Our Group	Advanced RET+ solid tumor	Phase 1/2	Jul 2021
HEC169096	Sunshine Lake Pharma	NSCLC, MTC and other solid tumors	Phase 1/2	Jun 2022
TY-1091	TYK Medicines	NSCLC, MTC and other advanced solid tumors	Phase 1/2	Dec 2022

Note:

(1) Only companies with drug right are listed.

Sources: CDE, Frost & Sullivan

For a competitive advantages analysis of selective RET inhibitors, see “Business – Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A400 – Competitive Advantages.”

INDUSTRY OVERVIEW

CHINA’S JAK INHIBITOR MARKET

Overview

Janus kinases (JAKs) are key enzymes responsible for transducing cytokine signals via the JAK-STAT pathway, which is a common pathway for many cytokines to modulate immune response and for the development of blood cells. However, due to its central role in mediating immune-related signals, dysregulation of the JAK-STAT pathway is implicated in a wide range of diseases, including autoimmune diseases such as rheumatoid arthritis (RA) and alopecia areata (AA), as well as hematological cancers. Blocking the JAK-STAT pathway using JAK inhibitors is a promising approach for treating a broad range of indications, clinically validated by the approval of several JAK inhibitors for treating multiple autoimmune diseases and certain hematological cancers. See “Business – Our Pipeline – Non-Oncology Franchise – A223 – Mechanism of Action” for details regarding the mechanism of action of JAK inhibitors in RA and AA.

Addressable Market Size of JAK Inhibitors

The JAK inhibitor market in China grew from RMB0.1 billion in 2017 to RMB2.0 billion in 2022 at a CAGR of 80.9%. Driven by an increasing addressable patient population, potential indication expansion and the anticipated market entry of novel JAK inhibitors, China’s JAK inhibitor market is projected to expand rapidly in the near future, reaching RMB22.1 billion in 2030 at a CAGR of 35.1%.

RA

RA is a prevalent chronic systemic autoimmune disease. It is characterized by chronic inflammation in the joints that gradually damages joint tissues as the disease progresses, leading to potentially debilitating symptoms including joint stiffness, pain and swelling that compromise patients’ quality of life.

Prevalence

RA affects a large population in China. The prevalence of RA in China increased from 5.8 million in 2017 to 6.0 million in 2022, and is expected to reach 6.2 million in 2030.

Treatment Paradigm

There is currently no cure for RA. The management of RA in China aims to achieve low disease activity or remission and to control joint damage and pain via long-term use of disease-modifying anti-rheumatic drugs (DMARDs). Currently, the 1L treatment for RA is conventional synthetic DMARD (csDMARD) monotherapy with methotrexate (MTX) recommended as the first choice when it is not contraindicated. The 2L treatment options include the addition of either a biologic DMARD (bDMARD) such as a TNF inhibitor, or a JAK inhibitor to the csDMARD.

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Compared to bDMARDs that target individual cytokines, JAK inhibitors can simultaneously interrupt the downstream signaling of multiple cytokines, which potentially underlies their effectiveness in RA patients who have failed multiple csDMARDs/bDMARDs therapies. Moreover, bDMARDs are large proteins that may cause immunogenicity, i.e., evoking an undesirable immune response, and require either intravenous infusion or subcutaneous injection for dosing. Conversely, JAK inhibitors are small molecules that are non-immunogenic and can be administered orally, thus potentially improving ease of dosing and treatment compliance. However, the approved JAK inhibitors have major safety issues, with black box warning issued by the FDA for increased risks of serious side effects including serious infection, death, malignancy, thrombosis, and major adverse cardiovascular events. This underscores a significant unmet need for novel JAK inhibitors with improved safety profile.

AA

AA is a common, distressing autoimmune disease characterized by transient, non-scarring hair loss due to an abnormal immune system that attacks hair follicles. Patients with AA tend to have a variable, relapsing-remitting disease course with multiple episodes of hair loss.

Prevalence

AA affects a large population in China with a rising prevalence. The prevalence of AA in China grew from 3.5 million in 2017 to 4.0 million in 2022 and is projected to reach 4.5 million in 2030.

Treatment Paradigm

In China, treatment options for AA are limited with only Minoxidil, a potassium channel opener, and Olumiant approved as the only disease-specific treatments for severe AA. Inhibiting JAK1/2 represents a clinically proven strategy for AA, underlined by the FDA approval of Olumiant (baricitinib) as the first and only systemic treatment for severe AA and its recent NMPA approval for the same indication.

Competitive Landscape of JAK Inhibitors

As of the Latest Practicable Date, there were three JAK inhibitors approved by the NMPA for treating RA and seven JAK inhibitor candidates in phase 2 or beyond for treating the same indication in China. The JAK inhibitor market for treating AA is emerging with Olumiant recently approved in March 2023 and four JAK inhibitor candidates, in phase 2 or beyond as of the Latest Practicable Date. The following tables summarize the competitive landscape of JAK inhibitors in China.

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Marketed Selective JAK Inhibitors in China

Brand name (Generic name)	Company	Targets	Indication	NMPA approval date	Treatment line	2023 NRDL status	2022 Revenue ⁽¹⁾ (RMB in millions)	2022 Market share ⁽²⁾
Xeljanz (Tofacitinib)	Pfizer	JAK1	RA	Mar 2017	2L			
			Ankylosing spondylitis	Apr 2022	2L/3L	Yes	N/A	6.0%
			Psoriatic arthritis	Oct 2022	1L			
Jakafi (Ruxolitinib)	Novartis	JAK1, JAK2	Myelofibrosis	Mar 2017	2L	Yes	N/A	42.3%
			Graft-versus-host disease	Mar 2023	2L	No		
Olumiant (Baricitinib)	Eli Lilly and Company	JAK1, JAK2	RA	Jun 2019	–	Yes	N/A	11.6%
			AA	Mar 2023	–	No		
Rinvoq (Upadacitinib)	AbbVie	JAK1	Atopic dermatitis	Feb 2022	2L			
			RA	Mar 2022	2L	Yes		
			Psoriatic arthritis	Apr 2022	2L		N/A	0.1%
			Ulcerative colitis	Feb 2023	N/A	No		
Cibinqo (Abrocitinib)	Pfizer	JAK1	Atopic dermatitis	Apr 2022	–	Yes	N/A	0.3%

Notes:

- (1) According to the disclosure in 2022 annual report.
- (2) In China’s JAK inhibitor market.

Sources: NMPA, drug label, NRDL, Frost & Sullivan

INDUSTRY OVERVIEW

JAK Inhibitor Candidates for RA and AA under Clinical Development in China (phase 2 or beyond)

Drug code	Company	Indication	Clinical stage	First posted date
ASP015K (peficitinib)	Astellas Pharma	RA	NDA registration	Jul 2018
PF-06651600 (ritlecitinib)	Pfizer	AA	NDA registration	Jun 2019
Jaktinib	Zelgen Biopharmaceuticals	Moderate-to-severe AA	Phase 3	Jun 2021
SHR0302	Jiangsu Hengrui Medicine	Moderate-to-severe RA	Phase 3	May 2020
		Severe adult AA	Phase 3	Jan 2022
LW402	Longwood Biopharmaceuticals	Moderate-to-severe RA	Phase 2	Nov 2022
A223	Our Group	Moderate-to-severe RA	Phase 2	Dec 2020
		Severe AA	Phase 2	Aug 2022
WXFL10203614	Wuxi Fortune Pharmaceutical	Moderate-to-severe RA	Phase 2	Dec 2020
LNK01001	Lynk Pharmaceuticals	Moderate-to-severe RA	Phase 2	Sep 2021
TLL-018	GaoLing Pharmaceutical Company	RA	Phase 2	Nov 2021

Sources: CDE, Frost & Sullivan

For a competitive advantages analysis of the JAK inhibitor candidates, see “Business – Our Pipeline – Non-Oncology Franchise – A223 – Competitive Advantages.”

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the major markets for which our drug candidates are positioned. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. We have agreed to pay Frost & Sullivan a total fee of RMB0.88 million for the preparation of the Frost & Sullivan Report, and we believe that such fees are consistent with the market rate. 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].

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We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the pharmaceutical market for potential [REDACTED]. 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 may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business.

Regulatory Authorities

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration (國家藥品監督管理局) (the “NMPA”), the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the “NHC”) and the National Healthcare Security Administration (國家醫療保障局) (the “NHSA”).

The NMPA is an authority under the State Administration for Market Regulation (國家市場監督管理總局) (the “SAMR”) and is the primary regulator for medical products. It is primarily responsible for the supervising and managing drugs, medical devices and cosmetics, including drafting of relevant regulations and policies; undertaking standard management, registration regulation, quality management and post-market risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics; undertaking management of qualifications for licensed pharmacists.

The NHC is primary national regulator for public health. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

The NHSA is an authority directly under the State Council responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

REGULATORY OVERVIEW

Laws and Regulations in Relation to Drug Manufacturer

Drug Manufacturing Permit

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) in September 1984 and lastly amended in August 2019 and came into effect in December 2019, the state adopts an industry entry permit system for drug manufacturers. The conduct of drug manufacturing activities shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people’s government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

Good Manufacturing Practices

Prior to December 1, 2019, establishment of a new drug manufacturer, construction of new production premise for a drug manufacturer or production of new dosage form are required to submit application for good manufacturing practice certification (GMP certification) with the drug regulatory authority in accordance with relevant provisions. If the Good Manufacturing Practices are satisfied, a GMP certificate will be issued. Pursuant to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Good Manufacturing Practices (《藥品生產質量管理規範》), promulgated by the Ministry of Health of the PRC (the “MOH”, now known as the NHC) in March 1988, newly amended in January 2011 and came into effect in March 1, 2011, provided guidance for the quality management, organization and staffing, production premises and facilities, equipments, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a manufacturer in a systematical manner.

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Laws and Regulations in Relation to New Drugs

Application for New Drug Registration

Drug registration refers to an approval process where the NMPA conducts review of the safety, efficacy and quality controllability of the drugs intended for marketing according to the application for drug registration made by an applicant, and decides whether to approve the application. Drug registration applications include new drug application, generic drug application, imported drug registration application and supplementary application, as well as re-registration application. Pursuant to the provisions of the Measures for the Administration of Drug Registration (2020) (《藥品註冊管理辦法》(2020)), promulgated by the SAMR in January 22, 2020 and came into effect in July 1, 2020, the Measures for the Administration of Drug Registration (2020) shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. In accordance with the Measures for the Administration of Drug Registration (2020), drugs registration refers to activities that a drug registration applicant files an application and other supplementary applications for clinical drug trial, approval for drug marketing, and re-registration, among others, under the legal procedures and according to the relevant requirements, and that the medical products administrative department examines the safety, effectiveness, and quality controllability based on the laws and regulations, and the existing scientific cognitions, to decide whether to agree with the activities applied for. A drug registration certificate shall be valid for five years. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

Non-clinical Research and Animal Testing

The non-clinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the SFDA in August 2003 and latest amended by CFDA in July 2017 and came into effect on September 1, 2017. The SFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) in April 2007, which specifies the requirements for institutions applying for Good Laboratory Practice (GLP) certification of non-clinical laboratory studies. On January 19, 2023, the NMPA amended the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), which is expected to come into effect on July 1, 2023.

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission in November 1988 and lastly amended in March 2017 by the State Council, the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State

REGULATORY OVERVIEW

Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities in December 2001 and came into effect in January 2002, performing conservation, breeding, production, supply, transportation and related commercial operations of experimental animals and related products requires a Certificate for Production of Laboratory Animals. A Certificate for Production of Laboratory Animals shall be valid for five years, and the holder shall apply for renewal six months prior to the expiry of the validity period.

Application for Clinical Trial

After completing the preclinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of new clinical drug trials. According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017 and came into effect on May 1, 2017, the decision on the approval of clinical trials of drugs enacted by the CFDA can be made by the Center for Drug Evaluation (the "CDE") from May 1, 2017. Pursuant to the Drug Administration Law, the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data and the samples, shall, in accordance with the regulations of the drug regulatory authority under the State Council be truthfully submitted to the said department for approval before clinical drug trial is conducted. The drug regulatory authority of under State Council shall decide whether to approve the clinical trial application and notify the decision to the clinical trial applicant within 60 business days from the date of accepting the clinical trial application. If the drug regulatory authority under the State Council fails to do so, the clinical trial application shall be deemed as approval, and if the bioequivalence test is conducted, it is required to report it to the drug regulatory authority under State Council for filing.

Before conducting the clinical trial, the applicant shall file a series of detailed documents with the NMPA. According to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013, and the Standard for the Management of Drug Clinical Trial Registration and Information Disclosure (Trial) (《藥物臨床試驗登記與信息公示管理規範(試行)》), all clinical trials approved by the CFDA and conducted in the PRC shall complete the clinical trial registration and information disclosure on the Drug Clinical Trial Information Platform. The applicant must complete the initial registration of the trial within one month after obtaining the approval of the clinical trial to obtain the unique registration number of the trial; and complete the subsequent data registration before the first patient is enrolled and submit it for the first time for disclosure.

After obtaining clinical trial approval, the applicant shall choose institutions qualified for clinical trials of the drug to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the

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territory PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

Clinical Trial

In compliance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), clinical trials are divided into Phase 1, Phase 2, Phase 3, Phase 4 and bioequivalence trial:

A clinical drug trial to be carried out shall be examined and approved by the ethics committee. The management of drugs used in a clinical drug trial shall satisfy the relevant requirements of the GCP. A sponsor approved to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the CDE.

Clinical trials shall be conducted for the application of new drug registration and shall be implemented in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), promulgated by the NMPA and NHC and came into effect on July 1, 2020. The Good Clinical Practice for Drug Trials stipulates the criteria for the entire procedure of the clinical trial including pre-clinical trial preparation and the necessary conditions, protection of testees' rights and interests, trial protocols, duties of researchers, duties of sponsors, duties of monitors, trial record and report, data management and statistical analysis, administration of drug products for trial, guarantee for quality, polycentric trials, with reference to the internationally recognized principles.

According to the Announcement of the National Medical Products Administration on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》), if a new drug clinical trial has been approved to be carried out, after the completion of Phase 1 and Phase 2 clinical trials and before the implementation of Phase 3 clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues including the design of the phase 3 clinical trial design. The applicant can also apply for communication on key technical issues at different stages of clinical research and development.

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New Drug Application

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), after completing the pharmaceutical research, pharmacological and toxicological research, clinical drug trial, and other researches supporting the marketing registration of a drug, determining the quality standards, completing the verification of commercial large-scale production process, and making sound preparation for the acceptance of drug registration inspection and examination, an applicant shall file an application for drug marketing authorization, and submit relevant research materials in accordance with the requirements of the application materials. After the formal examination of the application materials, an application that satisfies the requirements shall be accepted. Where a generic drug, in vitro diagnostic reagent managed as a drug, or any other eligible circumstance assessed by an applicant to be unnecessary or impossible for conducting clinical drug trial and meeting the conditions for exempting clinical drug trial, the applicant may directly file an application for drug marketing authorization. The technical guiding principles and relevant specific requirements for exempting clinical drug trial shall be developed and announced by the CDE.

The CDE shall organize pharmaceutical, medical and other technical personnel to evaluate the accepted applications for drug marketing authorization as required. Where the comprehensive evaluation conclusion is adopted, the drug shall be approved for marketing, and a drug registration certificate shall be issued. If the comprehensive evaluation conclusion is not adopted, a disapproval decision shall be made. A drug registration certificate shall specify the drug approval number, holder, manufacturer and other information. An over-the-counter (OTC) drug registration certificate shall also indicate the type of OTC drug.

Drug registration inspection means the inspection activities carried out for the development sites and production sites for verifying the authenticity and consistency of the application materials and the commercial production conditions for marketing of drugs, and examining the compliance of drug development, and data reliability, among others, and the extended examination activities carried out for manufacturers, suppliers, or other entrusted institutions of chemical active pharmaceutical ingredients (“APIs”), auxiliary materials, and packaging materials and containers in direct contact with drugs involved in the application for drug registration, if necessary.

The CDE shall decide whether to carry out on-site inspection of drug registration development based on risks, according to the degree of drug innovation and the previous acceptance of inspection by drug research institutions.

The CDE shall decide whether to launch production site inspection for drug registration based on risks according to the factors such as variety, process, facility, and previous acceptance of inspection for which an application is filed for registration. For innovative drugs, new modified drugs and biological products, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be

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conducted. For generic drugs, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted based on the risks, according to whether a drug production license for the corresponding production scope has been obtained and whether a variety of the same dosage form has been marketed.

After an application for drug registration is accepted, the CDE shall conduct preliminary examination within 40 days of acceptance, notify the CDE of organizing inspection and provide the relevant materials required for inspection, where production site inspection for drug registration is required, and concurrently notify the applicant and the medical products administrative department of the province, autonomous region, or municipality in the place where the applicant or production enterprise is located. In principle, the Center for Inspection shall complete the inspection work 40 days prior to the expiry of the time limit for inspection, and report the inspection information, inspection results and other relevant materials to the CDE.

Drug registration examination shall include standard review and sample examination. Standard review means the laboratory assessment of the scientificity of the items set in the standards for the drug for which the applicant applies, the feasibility of the test methods, and the rationality of quality control indicators, among others. Sample examination means the laboratory examination carried out for samples according to the application of the applicant or the drug quality standards verified by the CDE.

The review period for an application for drug marketing authorization shall be 200 days. Within this 200 days period, the review period for the procedures for prioritized review and approval shall be 130 days, and the review period for the procedures for prioritized review and approval for clinically and urgently needed overseas-marketed drug for a rare disease shall be 70 days.

The following duration shall be excluded from the relevant work period: (i) time taken for the applicant to provide supplementary materials, to make correction upon examination as well as to verify manufacturing process, quality standards and literature in accordance with the requirements; (ii) delay in examination or inspection due to reason of the applicant, time taken for organizing expert advisory meetings; (iii) the suspended duration in the event of suspension of review and approval procedures pursuant to the provisions of laws and regulations; and (iv) time taken for overseas examination where such overseas examination is activated.

Reform of Evaluation and Approval System for Drugs

In August 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (《關於改革藥品醫療器械審評審批制度的意見》) (the “Reform Opinions”), which provides a framework for reforming the evaluation and approval system for drugs and indicates enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

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In November 2015, the CFDA promulgated the Announcement on Certain Policies for Drug Registration, Evaluation and Approval (《關於藥品註冊審評審批若干政策的公告》) (the “Certain Policies Announcement”), which further clarifies the measures and policies on simplifying and accelerating the approval process on the basis of the Reform Opinions.

Pursuant to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA in March 2017 and came into effect in May 2017, the clinical trial approval decisions on drugs (including domestic and imported) can be directly made by the CDE in the name of the CFDA; decisions on approval of drug supplementary applications (including domestic and imported); decisions on approval of re-registration of imported drugs.

The Evaluation and Approval Procedures for Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》), the Evaluation and Approval Procedures for Conditionally Approved Drugs (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》) and The Preferential Evaluation and Approval Procedures for Drug Marketing Authorization (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) promulgated by the NMPA in July 2020 and came into effect in July 2020, replace the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) promulgated by the CFDA in December 2017 and came into effect in December 2017, which further clarified the Accelerating Registration Procedures for Drugs.

Regulations of Biosimilars

In February 2015, the CFDA released the Technical Guidelines for R&D and Evaluation of Biosimilars (《生物類似藥研發與評價技術指導原則》) (the “Biosimilar Guidelines”), which outline the regulatory framework for biosimilars in China and provide the basic principles for the evaluation and management of biosimilars. It sets forth the definition of biosimilars and reference drugs, the requirements in relation to the selection of reference drugs, the basic principles for the technical review, the criteria for comparability, and the conditions under which extrapolations of indications would be permissible. According to the Biosimilar Guidelines, biosimilars refer to therapeutic biological products that are similar to approved and registered reference drugs in terms of quality, safety and efficacy. The R&D and marketing of biosimilars need to comply with the relevant regulations of the PRC Drug Administration Law (《中華人民共和國藥品管理法》) and the Administrative Measures for Drug Registration (《藥品註冊管理辦法》). After completion of preclinical studies, the applicant is required to propose an application for a clinical trial, and after receiving the approval to conduct a clinical trial, the applicant should complete the clinical trial in accordance with the clinical trial protocol. The applicant shall submit an application for a marketing authorization after completion of the clinical trials and related preparations.

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), drug registration shall be subject to registration and administration by categories, namely Chinese medicine, chemical medicine and biological products etc. Biological product registration shall be categorized in accordance with biological product innovative medicine,

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biological product improved new medicine, marketed biological products (including biosimilar), etc. In order to cooperate with the implementation of the Administrative Measures for Drug Registration, the NMPA formulated the Registration Classification of Biological Products and Requirements for Application Materials (《生物製品註冊分類及申報資料要求》), and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Materials part came into effect on October 1, 2020. According to the Registration Classification of Biological Products and Requirements for Application Materials, the biosimilars are classified as category 3.3.

On February 10, 2021, the NMPA issued the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) to further standardize the development and evaluation of biosimilars, which came into effect on the same day. According to the Technical Guidelines for similarity evaluation and indication extrapolation of Biosimilars, “similarity” refers to a drug candidate that is overall similar to a reference drug that is approved for registration and that does not present clinically meaningful differences in quality, safety, and efficacy, and “Indication Extrapolation” refers to a drug candidate that is overall similar to the reference drug when directly aligned to clinical trials showing that the candidate is clinically similar to the reference drug in at least one indication. It may then be possible to extrapolate scientific arguments for indication related study data and information in support of its use for other indications not directly studied as approved in China for the reference drug. The similarity evaluation of biosimilars should be carried out comprehensively from the perspective of pharmaceutical, non-clinical and clinical studies to determine the overall similarity, and should be carried out at different stages of biopharmaceutical studies.

The Technical Guidance for Clinical Pharmacology Studies of Biosimilars (《生物類似藥臨床藥理學研究技術指導原則》) issued by the CDE in February 2022 provides further guidance recommendations for clinical pharmacology studies of biosimilars in the framework of The Biosimilar Guidelines and the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars, in which it is clear whether the candidate and reference drugs have similarity in clinical pharmacology needs to be evaluated based on statistical methods; currently, the average bioequivalence statistical approach is generally recommended for the comparison of PK and PD parameters.

With respect to the application and approval process for imported biosimilars developed overseas, according to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), the application for registration of drugs produced overseas shall be filed in accordance with the requirements for the detailed classification and the corresponding application materials.

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Marketing Authorization Holder System

Pursuant to the Drug Administration Law and the Administrative Measures for Drug Registration, the state implements the drug marketing authorization holder system for drug management. After obtaining a drug registration certificate, an applicant shall be the drug marketing authorization holder. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

The drug marketing authorization holder shall proactively carry out post-marketing research on drugs, further confirm the safety, effectiveness and quality controllability of drugs, and strengthen the continuous management of marketed drugs. Where a drug registration certificate and its annex require the marketing authorization holder to carry out relevant research work after the drug is marketed, the marketing authorization holder shall complete the research within the prescribed time limit and file a supplementary application, undergo recordation formalities or report as required. After a drug is approved for marketing, the marketing authorization holder shall continue to conduct research on drug safety and effectiveness, undergo recordation formalities in a timely manner or file a supplementary application for revising the instructions according to the relevant data, and continuously update and improve the instructions and labels. According to the duties, the medical products administrative department may require the marketing authorization holder to revise the instructions and labels based on the monitoring of adverse drug reactions and the post-marketing reevaluation results of the drug.

The marketing authorization holder shall apply for re-registration six months prior to the expiry of the validity period of the drug registration certificate. An application for re-registration of a domestically produced drug shall be filed by the marketing authorization holder with the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government, and an application for re-registration of a drug produced overseas shall be filed by the marketing authorization holder with the Center for Drug Evaluation.

Transfer of Drug Marketing Authorisation

Pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), upon approval by the drug administrative department of the State Council, a drug marketing authorisation holder may transfer its drug marketing authorisation. The transferee shall possess the quality management, risk control and liability compensation competence to ensure drug safety, effectiveness and quality controllability, and perform the obligations of the drug marketing permit holder.

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), transfer of drug marketing authorisation by the holder shall declare by way of supplementary application, and implement upon approval.

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Pursuant to the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (《藥品上市後變更管理辦法(試行)》), drug post-marketing changes shall not have any adverse impact on the safety, effectiveness and quality controllability of drugs. In the case of an application for the change to a drug holder, the production site, prescription, production techniques and quality standards of the drugs shall be consistent with those of the original drugs. In the case of any change, after the change of the holder has been approved, the holder after the change shall conduct full study, evaluation and necessary verification and shall implement or report such changes upon approval or filing as required.

In the case of an application for the change of a holder of domestically manufactured drugs, the transferee shall, after obtaining the drug manufacturing permit for the corresponding production scope, submit a supplementary application to the CDE. In particular, in the case of an application for the change of a holder of narcotic drugs or psychotropic drugs, the transferee shall also meet the requirements for the quantity and layout of the designated manufacturers of narcotic drugs and psychotropic drugs as determined by the NMPA.

The CDE shall make a decision on whether to approve the change within the prescribed time limit. If the change is approved, the CDE shall issue a supplementary drug application notice with the drug approval number and the valid period of the certificate remains unchanged. The CDE shall also send a copy thereof to the provincial drug regulatory authority at the place where the transferor, the transferee and the manufacturer are located.

The holder after the change shall have a production quality management system that meets the requirements specified in the GMP, undertake the obligations for the management of the drug in the whole life cycle, complete the continuous research work of the drug, ensure that the existing technical requirements are met after the drug is manufactured and marketed, and emphasis the situation of the transferred drug in its initial annual report.

The transferred drug may be sold on the market after passing the inspection for compliance with the GMP and fulfilling the product release requirements.

The provincial drug regulatory authority at the place where the transferee is located shall focus on strengthening the supervision and inspection of the transferred drugs and timely incorporate such supervision and inspection into the daily supervision plan.

Gathering, Collection and Filing of Human Genetic Resources

The Interim Measures for the Management of Human Genetic Resources set out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of

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Science and Technology in August 2015, foreign investment sponsors who gather and collect human genetic resources through clinical trials should file a record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通告》) in October 2017 and came into effect in December 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the listing of drugs in China.

Pursuant to the Regulations on the Management of Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations.

On October 17, 2020, SCNPC promulgated Biosecurity Law of the PRC (《中華人民共和國生物安全法》), taking effect from April 15, 2021. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbe laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. As per the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of China, upon obtaining the approval or record-filing. The establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law. In addition, (i) collecting human genetic resources of important genetic families or specific areas in China, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent department of science and technology under the State Council, (ii) preserving China’s human genetic resources, (iii) using China’s human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China’s human genetic resource materials out of the country shall subject to approval of the competent department of science and technology.

The Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (Exposure Draft) (《人類遺傳資源管理條例實施細則(徵求意見稿)》) for public comments on March 21, 2022. The aforementioned exposure draft has refined the Administrative Regulations on Human Genetic Resources of the

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People’s Republic of China, including but not limited to refining the definition of “human genetic resources information”, improving the identification standard of “foreign entities”, adjusting the scope of application of collection licensing, adjusting and improving the approval procedures for international cooperative scientific research and administrative supervision rules. As of the Latest Practicable Date, it has no legal effect.

Good Clinical Practice Certification and Compliance with the Good Clinical Practice (GCP)

To improve the quality of clinical trials, the NMPA and NHC promulgated the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the “GCP”) in April 2020 and came into effect on July 1, 2020, which aims to ensure that the clinical trials of drugs are standardized and the results are scientific and reliable, protecting the rights and safety of human subjects. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) promulgated by the general offices of the Chinese Communist Party Central Committee and the State Council in October 2017, the qualification of clinical trial institutions shall be subject to record management. Clinical trials should follow GCP and protocols approved by the ethics committee of each research center. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by the NMPA and NHC and came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is responsible for setting up a filing management information platform for drug clinical trial institution for registration and filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

Other Laws and Regulations in Relation to Medical Industry

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Programme (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) promulgated by the National Development and Reform Commission (the “NDRC”), the SDA and other authorities, came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to the Guiding Opinions on the Pilot of Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點

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的指導意見》) promulgated by the State Council on July 10, 2007, urban residents (not urban employees) in the pilot areas can voluntarily participate in the basic medical insurance for urban residents. Pursuant to the Opinions of the State Council on the Integration of the Basic Medical Insurance System for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents’ medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee’s basic medical insurance.

Medical Insurance Catalogue

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. A pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in the Pharmacopoeia of the PRC (current edition) (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. According to the Opinions of the NHSA and the Ministry of Finance on Establishing a List-Based System for Healthcare Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), which came into effect in January, 2021, all provinces shall implement the NRDL in a strict manner, and shall not have the discretion to formulate the catalogue or increase the drugs in any form, or adjust the scope of limited payment unless explicitly stipulated. After several adjustments, the currently effective one is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2022) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2022年)》) came into effective since January 13, 2023.

Drug Price

Pursuant to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council’s pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發〈推進藥品價格改革意見〉的通知》) jointly promulgated by NDRC, NHC, the Ministry of Human Resources and Social Security, Ministry of Industry and Information Technology, the Ministry of Finance, the MOFCOM and the CFDA on May 4, 2015. From June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be cancelled.

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Advertising of Pharmaceutical Products and Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which promulgated by SAMR and came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents. Holders of registration certificates or filing certificates of drugs, medical devices, health food and formula food for special medical purposes as well as the production enterprises and operating enterprises authorized by such holders of certificates shall be applicants for advertising (the “applicants”). Applicants may entrust agents to apply for the review of advertisements for drugs, medical devices, health food and formula food for special medical purposes. Applicants may submit their applications at the acceptance windows of advertisement review authorities, or may submit their applications for advertisements for drugs, medical devices, health food and formula food for special medical purposes via letters, faxes, e-mails or e-government platforms. The advertisement review authorities shall review the materials submitted by the applicant and shall complete the review within ten working days from the date of acceptance. After review, for that advertisements that are in line with laws, administrative regulations and these Measures, approval decisions of review shall be made and advertisement approval numbers shall be issued. The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which promulgated by SFDA and came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SFDA. A drug insert sheet should include the important scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug’s name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug’s name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindications, precautions, storage, production date, batch number, expiry date, approval number and drug manufacturer. Pursuant to the Measures for The Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards. If no national or professional standards are available, the enterprise can formulate its standards and put into implementation after obtaining the approval of the food and drug administration and bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its packaging standard. Drugs that without packing standards must not be sold or traded (except for drugs for the military).

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Drug Technology Transfer

Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer as the transferee and the application for drug registration by the drug manufacturer as the transferee pursuant to the laws and regulations in relation to drug technology transfer. The standardization of the registration process of drug technology transfer, which includes application for, evaluation, review, approval and supervision of drug technology transfer registration, is regulated by the Administrative Measures for Drug Registration and the Administrative Regulation for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》) promulgated by the SFDA on August 19, 2009. According to the above regulations, drug technology transfer includes new drug technology transfer and drug production technology transfer. An application for drug technology transfer must be submitted to the provincial drug regulatory authority, and the SFDA will ultimately make an approval decision based on the comprehensive opinions of the drug review center. Eligible applications will receive a letter of approval and a drug approval number for the supplementary application.

Laws and Regulations in Relation to Administration of Pathogenic Microorganism Laboratories

According to the Regulations on the Bio-safety Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全管理條例》) promulgated by State Council and latest amended in March 2018, the pathogenic microorganism laboratories are classified into Level 1, Level 2, Level 3 and Level 4 in accordance with its biosafety level for pathogenic microorganisms and the national standards for the bio-safety. Laboratories at Bio-safety Level 1 and Level 2 are forbidden to conduct experimental activities relating to any highly pathogenic microbes. Laboratories at Bio-safety Level 3 and Level 4 shall meet certain requirements to conduct experimental activities relating to any highly pathogenic microbes. Newly building, rebuilding or expanding of Bio-safety Level 1 or Level 2 laboratories shall file with the relevant health administrative department or veterinary administrative department in the municipal people’s government of the place where it is built. The laboratories of Bio-safety Level 3 and Level 4 shall be subject to the state accreditation for laboratories. Laboratories passing accreditation will be granted with Certificates for Bio-safety Laboratories at corresponding level. The certificate will be effective for five years.

Regulations in Relation to Intellectual Property

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》) (the “Patent Law”), which was promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 and came into effect on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) (the “Implementation Rules”), promulgated by the State Council on June 15, 2001 and latest amended on January 9, 2010 and came into effect on February 1, 2010. The Patent Law and

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The Implementation Rules provide for three types of patents, namely “invention,” “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years; the duration of a patent right for “utility model” is ten years; and the duration of a patent right for “design” is 15 years, all of which duration are from the date of application. According to the Patent Law, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaty participated by the PRC.

The newly amended Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the Patent Administration Department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed 14 years. Such newly adopted patent term extension rule benefits the Company through providing longer protection terms of patents applied or registered in the PRC and related to our product candidates. This rule needs to be further elaborated by the competent authority, and the benefits we could enjoy are subject to the relevant clarifications and explanations.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the PRC (《中華人民共和國商標法》), which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, and the Implementation Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which were promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014 and came into effect on May 1, 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of ten years to registered trademarks. When it is necessary to continue using the registered trademark upon expiration of period of validity, a trademark registrant shall make an application for renewal within 12 months before the expiration in accordance with the requirements. If such an application cannot be filed within that period, an extension period of six months may be granted. The period of validity for each renewal of registration shall be ten years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

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Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the MIIT, on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Regulations in Relation to Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”) promulgated by the National People’s Congress (the “NPC”) has come into effect. The Law of the PRC on Sino-Foreign Equity Joint Ventures and the Law of the PRC on Wholly Foreign-Owned and Law of the PRC on Sino-Foreign Cooperative Joint Ventures abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment and abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favourable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2021 Revision) (《外商投資准入特別管理措施(負面清單)(2021年版)》) issued by the NDRC and the MOFCOM on December 27, 2021, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements. While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the State Administration for Market Regulation, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, the MOFCOM is responsible for coordinating and guiding the reporting of foreign investment information nationwide. The competent commercial department of the local people’s government at or above the county level, as well as the relevant agencies of the Pilot Free Trade Zone and the National Economic and Technological Development Zone, are responsible for reporting information on foreign investment in the region. Foreign investors who directly or indirectly carry out investment

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activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancellation reports, and annual reports. Foreign investors who establish foreign invested enterprises in China or acquire domestic non-foreign-invested enterprises through equity merger and acquisition shall submit initial reports through the enterprise registration system when applying for the registration of the establishment of foreign-invested enterprises or applying for the registration of the change of the acquired enterprises. If the change in the information of initial reports involves registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system when applying for the registration or filing of change of enterprises. If the change in the information of initial reports does not involve registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system within 20 working days after the change. Foreign-invested listed companies may report information on changes in investors and their shareholdings only when the cumulative change in the foreign investors’ shareholding ratio exceeds 5% or the foreign parties’ shareholding or relative holding status have changed.

Regulations on Overseas Investment

Pursuant to the Administrative Measures for Outbound Investment (《境外投資管理辦法》) (Order No. 3 [2014] of the MOFCOM, effective on October 6, 2014) promulgated by the MOFCOM, the MOFCOM and provincial competent commerce departments shall carry out administration either by record-filing or approval, depending on different circumstances of outbound investment by enterprises. Outbound investment by enterprises that involves sensitive countries and regions or sensitive industries shall be subject to administration by approval. Outbound investment by enterprises that falls under any other circumstances shall be subject to administration by record-filing.

Pursuant to the Administrative Measures for Outbound Investment by Enterprises (《企業境外投資管理辦法》) (Order No. 11 of the NDRC, effective on March 1, 2018), a domestic enterprise (the “investor”) making an outbound investment shall obtain approval, conduct record-filing or other procedures applicable to outbound investment projects (the “Projects”), reporting relevant information, and cooperating with the supervision and inspection. Sensitive Projects carried out by Investors directly or through overseas enterprises controlled by them shall be subject to approval; non-sensitive Projects directly carried out by Investors, namely, non-sensitive projects involving investors’ direct contribution of assets or rights and interests or provision of financing or guarantee shall be subject to record-filing. The aforementioned “sensitive project” means a project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018 to list the current sensitive industries in detail. As of the Latest Practicable Date, we do not have any “sensitive Project” involving a sensitive country or region or a sensitive industry.

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Regulations in Relation to Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the SCNPC on February 22, 1993 and latest amended on December 29, 2018 (the “Product Quality Law”), is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable to compensate for any bodily injuries or damage to property other than the defective product itself resulting from the defects in the product, unless the manufacturer is able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall be liable to compensate for any bodily injuries or damage to property of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate neither the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder, producer or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and latest amended on October 25, 2013 and came into effect on March 15, 2014 to protect consumers’ rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. All business operators must pay high attention to protecting customers’ privacy and must strictly keep confidential any consumer information they obtain during their business operations.

Regulations in Relation to Production Safety

The Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC on June 29, 2002 and latest amended on June 10, 2021 and came into effect on September 1, 2021, is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the requirements may not engage in production and business operation activities. The production and business operation entities shall educate and train employees regarding production safety so as to ensure that the employees have the necessary knowledge of production safety, are familiar with the relevant regulations and rules for safe production and the rules for safe operation, master the skills of safe operation in their own positions, understand the emergency measures, and know their own rights and duties in

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terms of production safety. Employees who fail the education and training programmes on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project (the “construction project”) shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the construction project.

Regulations in Relation to Environmental Protection

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the SCNPC on December 26, 1989 and latest amended on April 24, 2014 and came into effect on January 1, 2015, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002 and latest amended on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 and latest amended on July 16, 2017 and came into effect on October 1, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

According to the Administrative Measures on Pollutant Emission Permits (Trial) (《排污許可管理辦法(試行)》), promulgated by the Ministry of Environmental Protection on January 10, 2018 and latest amended on August 22, 2019, enterprises, institutions and other producers and operators (the “**pollutant discharge enterprises**”) that have been included in the Classification Management List for Fixed Source Pollution Permits shall apply for and obtain a discharge permit in accordance with the prescribed time limit. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

Regulations in Relation to Prevention and Control of Occupational Diseases

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

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Regulations in Relation to Import and Export of Goods

According to the Provisions of the PRC on the Administration of Recordation of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》), promulgated by the General Administration of Customs of the PRC on November 19, 2021, which came into effect on January 1, 2022, where the consignee or consignor of imported or exported goods or a customs declaration enterprise applies for recordation, it shall obtain the qualification of market entities; particularly where the consignee or consignor of imported or exported goods applies for recordation, it shall be filed as a foreign trade business. Where the consignee or consignor of imported or exported goods or a customs declaration enterprise has undergone the formalities of recordation for customs declaration entities, branches that meet the requirements of the preceding paragraph may also apply for recordation for customs declaration entities.

Regulations in Relation to Overseas Securities Offering and Listing by Domestic Companies

On December 24, 2021, the CSRC released the Administrative Provisions of the State Council on the Overseas Offering and Listing of Securities 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(徵求意見稿)》) (the “Draft Listing Administrative Provisions”) and the Administrative Measures for the Recordation of Overseas Offering and Listing of Securities 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.

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 had become effective on March 31, 2023 (the “Implementation Date”). The Trial Measures, upon the Implementation Date, had comprehensively improved and reformed the prior regulatory regime for overseas offering and listing of PRC domestic companies’ securities, and had regulated 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.

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Regulations in Relation to the “Full Circulation” of H-Share

On November 14, 2019, CSRC announced the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (the “Guidelines for the ‘Full Circulation’”). According to the Guidelines for the “Full Circulation”, “Full circulation” means listing and circulating on the Stock Exchange of the domestic unlisted shares of an H-share listed company, including 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. 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”. Pursuant to Article 18 of the Overseas Listing Measures, which came into effect on March 31, 2023, for a domestic enterprise seeking direct overseas listing, shareholders holding such enterprise’s domestic unlisted shares who apply for the conversion of its domestic unlisted shares into overseas listed shares shall comply with the relevant provisions of the CSRC and entrust such domestic enterprise to file with the CSRC. After domestic unlisted shares are listed and circulated on the Stock Exchange, they may not be transferred back to China.

On December 31, 2019, CSDC and Shenzhen Stock Exchange (the “SZSE”) jointly announced the Measures for Implementation of H-share “Full Circulation” Business (《H股“全流通”業務實施細則》) (“Measures for Implementation”). The businesses of cross-border conversion registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. in relation to the H-share “Full Circulation” business, are subject to the Measures for Implementation. Where there is no provision in the Measures for Implementation, it shall be handled with reference to other business rules of the CSDC and China Securities Depository and Clearing (Hong Kong) Company Limited (the “CSDC (Hong Kong)”) and SZSE.

In order to fully promote the reform of H-shares “Full Circulation” and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDC has promulgated the Circular on Issuing the Guide to the Program for Full Circulation of H-shares (《關於發佈〈H股“全流通”業務指南〉的通知》) in February 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, etc.

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Regulations in Relation to Employment and Social Securities

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by the SCNPC on July 5, 1994 and latest amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), promulgated by the SCNPC on June 29, 2007 and latest amended on December 28, 2012 and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, working location, occupational hazards, and status of safe production as well as remuneration and other conditions.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and latest amended on December 29, 2018, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was amended by the State Council on March 24, 2019, employers and/or employees are required to contribute to a number of social security funds, including funds for basic pension insurance, employment insurance, basic medical insurance, occupational injury insurance, maternity leave insurance, and to housing provident funds. These payments are made to local administrative authorities and employers who fail to contribute may be fined and ordered to rectify within a stipulated time limit.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

Laws and Regulations in Relation to New Drug

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (the “PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension

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of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the preclinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (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 reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as Phase 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.

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- 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.

Specifically for oncology drugs and biologics, in August 2018, the FDA, together with other US competent authorities, introduced a draft guidance paper “*Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry*” (the “Guidance”), which was formally adopted in March 2022. This guidance paper acknowledges a new clinical trial design, which the FDA calls the first-in-human (“FIH”) multiple expansion cohort trial. These are trial designs that have a single protocol with an initial dose escalation phase for the initial determination of a tolerated dose and multiple concurrently accruing expansion cohorts with assessments that are more typical of phase 2 trials (i.e., to estimate anti-tumor activity). The new trial design is intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 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.

U.S. Review and Approval Processes

The results of product development, preclinical 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 an NDA or BLA. Unless deferred or waived, NDAs or 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 an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

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Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/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 NDA/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 NDA/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 NDA/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 NDA/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 NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product’s safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA’s Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product’s review based upon the product’s primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

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Expedited Development and Review Programs

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 preclinical and clinical data is as efficient as practicable.

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 NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (“REMS”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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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 NDA/BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

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 an NDA or 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 NDA/BLA submission, and all of the review phase, which is the time between NDA/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

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claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which an NDA or a BLA has not been submitted.

HISTORY AND CORPORATE STRUCTURE

OVERVIEW

We are an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally. Empowered by our integrated drug development capabilities and a well-established management system that covers all key business functionalities, we are dedicated to the development of differentiated treatments to improve the existing standard of care.

Our Company was established on November 22, 2016 as a joint stock company in Sichuan by Kelun Pharmaceutical and Employee Incentive Platforms. For further details of the incorporation and major shareholding changes of our Company, see “– Corporate History – Establishment and Major Shareholding Changes of Our Company” below.

MILESTONES

The following table summarizes various key milestones in our corporate and business development.

Year	Milestone
2016	Our Company was incorporated in Sichuan, China.
2018	We received IND approval from the NMPA and initiated a phase 1 clinical trial for A166. Our two 2,000 L single-use bioreactors and 300 L ADC conjugation tank were put into operation. We entered into a strategic license and collaboration agreement with Harbour BioMed.
2019	We launched the pivotal phase 2 clinical trial of A167 for RM-NPC. We received IND approvals from the FDA for the initiation of the global phase 1/2 clinical trial of SKB264.
2020	We received IND approvals from the NMPA for the initiation of the global phase 1/2 clinical trial of SKB264 for advanced solid tumors. We commenced A140’s pivotal phase 3 clinical equivalence trial for RAS wild-type mCRC for A140.

HISTORY AND CORPORATE STRUCTURE

<u>Year</u>	<u>Milestone</u>
2021	<p>We completed the Series A Financing.</p> <p>We commenced a pivotal phase 2 trial in China for A166 to treat advanced HER2+ BC.</p> <p>We submitted an NDA to the NMPA for A167 for RM-NPC.</p> <p>We entered into a license and collaboration agreement with Ellipses.</p>
2022	<p>We commenced a pivotal phase 3 trial in China for SKB264 in advanced TNBC patients.</p> <p>We granted to MSD an exclusive, royalty-bearing and sublicensable license to develop, use, manufacture and commercialize our TROP2 ADCs, including SKB264, and products containing one or more such TROP2 ADCs outside Greater China.</p> <p>We granted to MSD an exclusive, royalty-bearing, sublicensable license to develop, use, manufacture and commercialize SKB315, our CLDN18.2 ADC, and products based on SKB315 globally.</p> <p>We entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets for the treatment of cancer.</p> <p>We obtained IND approvals from the NMPA for two phase 2 clinical trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a 1L treatment for advanced TNBC.</p> <p>We received IND approvals from the NMPA and FDA for a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors.</p> <p>We are authorized by the NDRC to establish the “National Engineering Research Center of Targeted Biologics (生物靶向藥物國家工程研究中心)”.</p>

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<u>Year</u>	<u>Milestone</u>
2023	<p>We completed the Series B Financing.</p> <p>We received IND approval from the NMPA for SKB264’s phase 2 basket study as combination therapies for advanced EGFR wild-type and EGFR-mutant NSCLC.</p> <p>SKB264 was granted Breakthrough Therapy Designation for EGFR-TKI failed EGFR-mutant advanced NSCLC by the NMPA.</p> <p>We submitted an NDA to the NMPA for A166 for advanced HER2+ BC.</p>

CORPORATE HISTORY

Establishment and Major Shareholding Changes of Our Company

Our Company was established in Sichuan as a joint stock company on November 22, 2016 with an initial registered capital of RMB100.0 million. At the time of our establishment, our Company was owned as to 70.0% by Kelun Pharmaceutical, a global leading IV (intravenous) fluids solution products and antibiotics intermediates manufacturer whose shares are listed on the Shenzhen Stock Exchange (stock code: 002422), and 30% by four employee incentive platforms, namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide (the “**Employee Incentive Platforms**”) equally with each holding 7.5% of our then total issued shares. For details of our Employee Incentive Platforms, see “– Employee Incentive Platforms” below.

Since the establishment, our Company has undertaken a series of capital increases to, amongst others, raise funds for the development of our business and diversify our Shareholders base. The major shareholding changes of our Company are set out below.

1. Share Transfers with Dr. WANG Jingyi

On May 29, 2020, Dr. WANG Jingyi, entered into a share transfer agreement with Kelun Pharmaceutical, pursuant to which Kelun Pharmaceutical agreed to transfer 10% equity interest in our Company held by it to Dr. WANG Jingyi for incentive purpose at a nominal consideration of RMB1.00. The transfer was settled on May 30, 2020. On December 6, 2021, due to Mr. WANG Jingyi’s expected resignation as the general manager of our Company, Kelun Pharmaceutical and Dr. WANG Jingyi further entered into a share transfer agreement, pursuant to which Dr. WANG Jingyi agreed to transfer back 2,500,000 Shares and 1,800,000 Shares to Kelun Pharmaceutical at a nominal consideration of RMB1.00 by December 31, 2021 and January 31, 2022, respectively. Upon completion of the above share transfers, Dr. WANG Jingyi held an aggregate of 5,700,000 Shares in our Company.

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2. Pre-Series A Financing

On May 29, 2020, our Company, Kelun Pharmaceutical, the Employee Incentive Platforms, Dr. WANG Jingyi and Ningbo Daoyi Enterprise Consulting Management Co., Ltd. (寧波道奕企業諮詢管理有限公司) (“**Ningbo Daoyi**”) entered into a capital increase agreement, pursuant to which Ningbo Daoyi agreed to invest in our Company by subscribing for our registered capital of RMB4.2 million at the total subscription price of RMB12.6 million (the “**Pre-Series A Financing**”). The subscription price was determined based on arm’s length negotiation between the parties primarily taking into account the then valuation of our Company, and was fully settled on June 1, 2020. For further details of the Pre-Series A Financing, see “– Pre-[REDACTED] Investments” below.

Upon completion of the Pre-Series A Financing, our Company was owned by Kelun Pharmaceutical, the Employee Incentive Platforms, Dr. WANG Jingyi and Ningbo Daoyi as to approximately 57.6%, 28.8%, 9.6% and 4.0% respectively, and the registered capital of our Company was increased from RMB100.0 million to RMB104.2 million.

3. Series A Financing

On March 22, 2021, a share subscription agreement (“**Series A Share Subscription Agreement**”) was entered into among, our Company, Kelun Pharmaceutical, the Employee Incentive Platforms, Dr. WANG Jingyi, Mr. LIU Gexin (in his capacity as the actual controller of the Company), Ningbo Daoyi and the Series A Investors. Pursuant to the Series A Share Subscription Agreement, the Series A Investors agreed to subscribe for an aggregate of 11,850,609 Shares at the total subscription price of RMB511,782,500 (the “**Series A Financing**”), details of which are set out below:

Name of Series A Investors	Shares subscribed for	Consideration	Date on which consideration was fully settled	Approximately shareholding upon completion of the Series A Financing
Wealthy Linkage Limited (“ Wealthy Linkage ”)	5,251,275	USD35,000,000 (<i>equivalent to RMB226,782,500 according to the pre-determined foreign exchange rate</i>)	May 7, 2021	4.53%
Future Industry Investment Fund Phase II (Limited Partnership) (先進製造產業投資基金二期(有限合夥)) (“ FIIF ”)	5,210,000	RMB225,000,000	April 25, 2021	4.49%

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Name of Series A Investors	Shares subscribed for	Consideration	Date on which consideration was fully settled	Approximately shareholding upon completion of the Series A Financing
LAV Kecheng Hong Kong Limited (“LAV Kecheng”)	771,852	USD5,144,429.82 <i>(equivalent to RMB33,333,333 according to the pre-determined foreign exchange rate)</i>	April 23, 2021	0.67%
Suzhou Likang Equity Investment Center (蘇州禮康股權投資中心(有限合夥)) (“Suzhou Likang”)	385,926	RMB16,666,667	April 21, 2021	0.33%
Zhuhai Liangheng Equity Investment Partnership (Limited Partnership) (珠海良恒股權投資合夥企業(有限合夥)) (“Gao Ling Liangheng”)	231,556	RMB10,000,000	April 22, 2021	0.20%
Total	11,850,609	RMB511,782,500		10.21%

The relevant considerations were determined based on arm’s length negotiation between the parties primarily taking into account the then valuation of our Company, which was based on status of our business and the research and development progress of our pipelines at that time. Upon completion of the Series A Financing, our Company was owned as to approximately (i) 51.70% by Kelun Pharmaceutical, (ii) 25.85% by the Employee Incentive Platforms with each of the four entities subsisting the Employee Incentive Platforms holding approximately 6.46%; (iii) 8.62% by Dr. WANG Jingyi, (iv) 3.62% by Ningbo Daoyi, and (v) 10.21% by Series A Investors. The registered capital of our Company was increased from RMB104.2 million to RMB116,050,609. For further details of the Series A Financing, see “– Pre-[REDACTED] Investments” below.

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4. *Series B Financing*

Share Subscription by Kelun Pharmaceutical

On January 3, 2023, our Company, Kelun Pharmaceutical and the other then Shareholders of the Company entered into a share subscription and debt-to-equity swap agreement, pursuant to which Kelun Pharmaceutical agreed to further subscribe for an aggregate of 51,255,685 Shares at the total subscription price of RMB2.65 billion, among which RMB2.5 billion was settled through debt-to-equity swap and RMB0.15 billion was settled by cash on January 16, 2023 (the “**Share Subscription by Kelun Pharmaceutical**”). The consideration was based on arm’s length negotiations between our Company and Kelun Pharmaceutical and determined with reference to the cost per Share paid by external investors in connection with the Series B Financing, representing a fair and reasonable valuation of our Company by seasoned investors. Upon completion of the Share Subscription by Kelun Pharmaceutical, Kelun Pharmaceutical held an aggregate of 115,555,685 Shares in our Company, accounting for 59.75% of our Company’s share capital.

Investment by external investors

On January 3, 2023, a series of share subscription agreements (“**Series B Share Subscription Agreements**”) were entered into among, our Company, Kelun Pharmaceutical, the Employee Incentive Platforms, Dr. WANG Jingyi, Mr. LIU Gexin (in his capacity as the actual controller of the Company), Ningbo Daoyi, Series A Investors and Series B Investors. Pursuant to the Series B Share Subscription Agreements, the Series B Investors agreed to subscribe for an aggregate of 26,076,205 Shares at the total subscription price of RMB1,348,181,000 (the “**Series B Financing**”), details of which are set out below:

Name of Series B Investors	Shares subscribed for	Consideration	Date on which the consideration was fully settled
Merck Sharp & Dohme LLC (“MSD”)	13,443,693	USD100,000,000 <i>(equivalent to RMB695,060,000 according to the pre-determined foreign exchange rate)</i>	January 28, 2023

HISTORY AND CORPORATE STRUCTURE

Name of Series B Investors	Shares subscribed for	Consideration	Date on which the consideration was fully settled
Guangxi Kexin Lunda Investment Limited Partnership (廣西科信倫達投資合夥企業(有限合夥)) (“Kexin Lunda”)	2,321,012	RMB120,000,000	January 18, 2023
Wealthy Linkage	2,016,553	USD15,000,000 <i>(equivalent to RMB104,259,000 according to the pre-determined foreign exchange rate)</i>	January 20, 2023
Leyue Capital Limited (“Leyue Capital”)	2,016,553	USD15,000,000 <i>(equivalent to RMB104,259,000 according to the pre-determined foreign exchange rate)</i>	January 20, 2023
FIIF	1,934,177	RMB100,000,000	January 18, 2023
Anling Weijian Equity Investment (Zibo) Limited Partnership (安齡偉健股權投資(淄博)合夥企業(有限合夥)) (“Anling Weijian”)	967,088	RMB50,000,000	January 20, 2023
BOSC Xingling (Jiaxing) Equity Investment Partnership (上銀杏苓(嘉興)股權投資合夥企業) (“BOSC Xingling”)	734,987	RMB38,000,000	January 16, 2023
Gygnus Real Company Limited (“Gygnus Real”)	672,184	USD5,000,000 <i>(equivalent to RMB34,753,000 according to the pre-determined foreign exchange rate)</i>	January 19, 2023

HISTORY AND CORPORATE STRUCTURE

Name of Series B Investors	Shares subscribed for	Consideration	Date on which the consideration was fully settled
Chengdu Wutong Juke Enterprise Management Limited Partnership (成都梧桐聚科企業管理合夥企業 (有限合夥)) (“Wutong Juke”)	616,035	RMB31,850,000	January 19, 2023
Chengdu Wenjiang Emerging Industry Venture Capital Fund Limited Partnership (成都溫江新興產業創業投 資基金合夥企業(有限合夥)) (“Chengdu Wenjiang Emerging Industry Venture”)	386,835	RMB20,000,000	January 13, 2023
Cinda Capital Management Limited (信達資本管理有限公司) (“Cinda Capital”)	386,835	RMB20,000,000	January 13, 2023
Shenzhen Yunqi Xinneng Venture Investment Center Limited Partnership (深圳雲起欣能創業投資中 心(有限合夥)) (“Yunqi Xinneng”) / ZHOU Youcai (周有財) ^{Note}	386,835	RMB20,000,000	February 10, 2023
Chengdu Longyi Technology Co., Ltd. (成都隆一科技有限責任公司) (“Longyi Technology”)	193,418	RMB10,000,000	January 12, 2023
Total	26,076,205	RMB1,348,181,000	

Note: On January 3, 2023, as a part of the Series B Share Subscription Agreements, a share subscription agreement was signed by Yunqi Xinneng to subscribe for 386,835 Shares at a consideration of RMB20 million. On February 10, 2023, as an internal arrangement of Yunqi Xinneng, Yunqi Xinneng entered into a share transfer agreement with ZHOU Youcai (周有財), the sole limited partner of Yunqi Xinneng and an Independent Third Party, pursuant to which Yunqi Xinneng transferred all 386,835 Shares subscribed by it under the share subscription agreement to ZHOU Youcai, and the obligations of Yunqi Xinneng thereunder (including the obligation to pay the subscription price) were therefore assumed by ZHOU Youcai. On February 10, 2023, ZHOU Youcai fully settled the relevant subscription price with our Company.

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The relevant considerations were determined based on arm’s length negotiation between the parties primarily taking into account the then valuation of our Company, which was based on (a) status of our business and the research and development progress of our pipelines at that time; and (b) successful collaboration with first-tier multinational pharmaceutical companies in 2022. The register share capital of our Company was increased from RMB116,050,609 to RMB193,382,499. For further details of the Series B Financing, see “– Pre-[REDACTED] Investments” below. Upon completion of the Series B Financing (including the Share Subscription by Kelun Pharmaceutical), the shareholding structures of our Company are set out below:

Shareholder	Shares held upon completion of Series B Financing	Shareholding percentage upon completion of Series B Financing
Kelun Pharmaceutical	115,555,685	59.75%
Kelun Huicai	7,500,000	3.88%
Kelun Huineng	7,500,000	3.88%
Kelun Huizhi	7,500,000	3.88%
Kelun Huide	7,500,000	3.88%
Dr. WANG Jingyi	5,700,000	2.95%
MSD	13,443,693	6.95%
Wealthy Linkage ⁽¹⁾	7,267,828	3.76%
Leyue Capital ⁽¹⁾	2,016,553	1.04%
FIIF	7,144,177	3.69%
Ningbo Daoyi	4,200,000	2.17%
Kexin Lunda ⁽²⁾	2,321,012	1.20%
Cinda Capital ⁽²⁾	386,835	0.20%
LAV Kecheng ⁽³⁾	771,852	0.40%
Suzhou Likang ⁽³⁾	385,926	0.20%
Anling Weijian	967,088	0.50%
BOSC Xingling	734,987	0.38%
Gygnus Real	672,184	0.35%
Wutong Juke ⁽⁴⁾	616,035	0.32%
Chengdu Wenjiang Emerging Industry Venture ⁽⁴⁾	386,835	0.20%
ZHOU Youcai	386,835	0.20%
Gao Ling Liangheng	231,556	0.12%
Longyi Technology	193,418	0.10%
Total	193,382,499	100%

Notes:

- (1) Wealthy Linkage and Leyue Capital are companies managed by IDG Capital. For more details on Wealthy Linkage and Leyue Capital, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (2) The beneficial owner of Kexin Lunda and Cinda Capital is China Cinda Asset Management Co., Ltd. (Stock Code: 01359 and 04621 (preference shares)). For more details on Kexin Lunda and Cinda Capital, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.

HISTORY AND CORPORATE STRUCTURE

- (3) Each of LAV Kecheng and Suzhou Likang is an investment arm of Lilly Asia Ventures. For more details on LAV Kecheng and Suzhou Likang, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (4) The beneficial owner of Chengdu Wenjiang Emerging Industry Venture and Wutong Juke is Bureau of State-owned Assets Supervision and Administration of Wenjiang District of Chengdu (成都市溫江區國有資產監督管理局). For more details on Chengdu Wenjiang Emerging Industry Venture and Wutong Juke, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.

PRC Legal Advisor’s Confirmation

As advised by our PRC Legal Advisor, the increases of registered capital and share transfers in respect of our Company as described above had been completed and registered with competent local branches of SAMR.

Kelun Research Institute Assets Transfer

Our Company was established by Kelun Pharmaceutical and Employee Incentive Platforms. To optimize the business delineation of different members within Kelun Group and better support our Company as an independent platform for innovative drugs, on March 21, 2019, our Company and Kelun Research Institute, a wholly owned subsidiary of Kelun Pharmaceutical, entered into an assets transfer agreement (the “**Kelun Research Institute Assets Transfer Agreement**”), pursuant to which the patents, know-hows and associated intellectual property rights related to R&D of novel drugs previously owned by Kelun Research Institute and the relevant equipment used in connection with R&D of novel drugs were transferred from Kelun Research Institute to our Company (the “**Kelun Research Institute Assets Transfer**”). The transfer price under the Kelun Research Institute Assets Transfer Agreement amounted to approximately RMB405.3 million (the “**Kelun Research Institute Assets Transfer Price**”), which was determined through arm’s length negotiation between the parties with reference to a valuation report issued by an Independent Third Party valuer. As of the Latest Practicable Date, (i) the Kelun Research Institute Assets Transfer Price had been fully settled by our Company; and (ii) all the transfers under the Kelun Research Institute Assets Transfer Agreement had been duly completed.

On October 14, 2021, the Company and Kelun Research Institute entered into an asset transfer agreement (the “**A166 Transfer Agreement**”), pursuant to which patents, know-how and associated intellectual property rights related to A166 previously owned by Kelun Research Institute was transferred to the our Company (the “**A166 Transfer**”). The consideration for the A166 Transfer amounted to approximately RMB14.4 million and was determined through arm’s length negotiation between the parties with reference to a valuation report issued by an Independent Third Party valuer. As of the Latest Practicable Date, (i) the consideration for the A166 Transfer had been fully settled by our Company; and (ii) the A166 Transfer had been duly completed. The transfer of A166 was separately arranged and completed after the execution of the Kelun Research Institute Assets Transfer Agreement, primarily due to extensive discussions with the various Independent Third Parties to the contract, which delayed the transfer process.

HISTORY AND CORPORATE STRUCTURE

Upon completion of the transfers under the Kelun Research Institute Assets Transfer Agreement, the Remaining Kelun Group primarily focuses on (i) manufacturing of IV fluids solution products and antibiotics intermediates, and (ii) research and development of generic drugs, which are mainly carried out through Kelun Research Institute. In contrast, our Company primarily focuses on the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally. Our Directors believe that there is a clear business delineation of business between our Group and the Remaining Kelun Group. Please see “Relationship with Our Controlling Shareholders” in this document for details.

EMPLOYEE INCENTIVE PLATFORMS

In recognition of the contributions of our employees and to incentivize them to further promote our development, and considering the restriction on the number of limited partners of a limited partnership under the relevant PRC law (i.e. no more than 50), multiple limited partnerships namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide were established in the PRC as our employee incentive platforms.

Kelun Huicai

Kelun Huicai was established in the PRC as a limited partnership on August 26, 2016. Chengdu Kelun Jingchuan Technology Co., Ltd. (成都科倫晶川科技有限公司) (“**Kelun Jingchuan**”), a wholly-owned subsidiary of Kelun Pharmaceutical, is the sole general partner of Kelun Huicai and is responsible for the management of Kelun Huicai. As of the Latest Practicable Date, Kelun Huicai had 37 limited partners, including Dr. GE Junyou (our executive Director and general manager), Mr. FENG Hao (our non-executive Director), Dr. QING Yan (our supervisor), Mr. LAI Degui (our supervisor), Ms. LIAO Yihong (our supervisor), Mr. FENG Yi (our deputy general manager, chief strategy officer and senior vice president) and 31 other key employees who are directors or managers of core R&D departments, manufacturing and quality departments and other supporting departments of our Group. As of the Latest Practicable Date, Kelun Huicai subscribed for approximately 3.88% of the registered capital of our Company. The voting rights attaching to the Shares held by Kelun Huicai are exercisable by the general partner of Kelun Huicai in accordance with the partnership agreement entered into among the general and limited partners of Kelun Huicai.

Kelun Huineng

Kelun Huineng was established in the PRC as a limited partnership on August 26, 2016. Kelun Jingchuan is the sole general partner of Kelun Huineng and is responsible for the management of Kelun Huineng. As of the Latest Practicable Date, Kelun Huineng had 38 limited partners, including Ms. YANG Qiuyan (our supervisor), Dr. ZHANG Yiwei (our deputy general manager), Dr. TAN Xiangyang (our deputy general manager and chief scientific officer), Dr. JIN Xiaoping (our deputy general manager and chief scientific officer) and 34 other key employees who are directors or managers of core R&D departments, manufacturing and quality departments and other supporting departments of our Group. As of the Latest Practicable Date, Kelun Huineng subscribed for approximately 3.88% of the registered capital of our Company. The voting rights attaching to the Shares held by Kunlun Huineng are exercisable by the general partner of Kelun Huineng in accordance with the partnership agreement entered into among the general and limited partners of Kelun Huineng.

HISTORY AND CORPORATE STRUCTURE

Kelun Huizhi

Kelun Huizhi was established in the PRC as a limited partnership on August 26, 2016. Kelun Jingchuan is the sole general partner of Kelun Huizhi and is responsible for the management of Kelun Huizhi. As of the Latest Practicable Date, Kelun Huizhi had 42 limited partners, including Dr. SONG Hongmei (our supervisor) and 41 other key employees who are directors or managers of core R&D departments, manufacturing and quality departments and other supporting departments of our Group. As of the Latest Practicable Date, Kelun Huizhi subscribed for approximately 3.88% of the registered capital of our Company. The voting rights attaching to the Shares held by Kunlun Huizhi are exercisable by the general partner of Kelun Huizhi in accordance with the partnership agreement entered into among the general and limited partners of Kelun Huizhi.

Kelun Huide

Kelun Huide was established in the PRC as a limited partnership on August 26, 2016. Kelun Jingchuan is the sole general partner of Kelun Huide and is responsible for the management of Kelun Huide. As of the Latest Practicable Date, Kelun Huide had 43 limited partners, including Mr. ZHOU Zejian (our chief financial officer and the secretary of the Board) and 42 other key employees who are directors or managers of core R&D departments, manufacturing and quality departments and other supporting departments of our Group. As of the Latest Practicable Date, Kelun Huide subscribed for approximately 3.88% of the registered capital of our Company. The voting rights attaching to the Shares held by Kunlun Huide are exercisable by the general partner of Kelun Huide in accordance with the partnership agreement entered into among the general and limited partners of Kelun Huide.

OUR SUBSIDIARIES

Sichuan Konas

Sichuan Konas was established as a limited liability company in the PRC on September 30, 2016 with a registered capital of RMB4.0 million. At the time of its establishment, Sichuan Konas was wholly owned by Kelun International Pharmaceutical (Holding) Co., Limited (“**Kelun International**”), a subsidiary of Kelun Pharmaceutical. On May 29, 2020, Kelun International transferred all its equity interest in Sichuan Konas to our Company at a nil consideration. As of the Latest Practicable Date, Sichuan Konas had no substantive business.

KLUS PHARMA

KLUS PHARMA was incorporated under and pursuant to the laws of the State of New Jersey on October 31, 2014 with an authorized share capital of US\$100 divided into 10,000 common shares. At the time of its incorporation, KLUS PHARMA was wholly owned by Kelun International Development Co. Limited (“**Kelun Development**”), a subsidiary of Kelun Pharmaceutical. On May 29, 2020 and September 9, 2020, as a part of the Kelun Research Institute Assets Transfer, Kelun Development and our Company entered into a share transfer

HISTORY AND CORPORATE STRUCTURE

agreement and a supplemental agreement, pursuant to which Kelun Development agreed to transfer all shares of KLUS PHARMA held by it to our Company at a consideration of US\$42.62 million, which was determined through arm’s length negotiation between the parties with reference to a valuation report issued by an Independent Third Party valuer. The consideration of the acquisition has been settled on November 30, 2020. The acquisition has been properly and legally completed and settled with applicable regulatory approvals having been obtained. As of the Latest Practicable Date, KLUS PHARMA mainly engaged in the business development of our products.

Kelun-Biotech Research Center

Kelun-Biotech Research Center was established as a limited liability company in the PRC on March 30, 2023 with a registered capital of RMB100 million. It is wholly owned by our Company. As of the Latest Practicable Date, Kelun-Biotech Research Center had no substantive business.

For share capital changes of our subsidiaries, see “Appendix VII – Statutory and General Information – A. Further Information about Our Group – 3. Subsidiaries of our Company and Changes in Share Capital of Our Subsidiaries.”

PRE-[REDACTED] INVESTMENTS

Principal Terms of the Pre-[REDACTED] Investments

	Pre-Series A Financing	Series A Financing	Series B Financing
Date of agreement	May 29, 2020	March 22, 2021	January 3, 2023
Date on which the consideration was fully settled	June 1, 2020	May 7, 2021	February 10, 2023
Cost per Share	RMB3.00	RMB43.19	RMB51.70
Amount of Shares subscribed for	4,200,000	11,850,609	26,076,205 ⁽¹⁾
Funds raised by our Group	RMB12.6 million	RMB511.8 million	RMB1,348.2 million ⁽¹⁾
Post-money Valuation of our Company ⁽²⁾	RMB312.6 million	RMB5.0 billion	RMB10.0 billion
Discount to the [REDACTED] of the indicative [REDACTED] range ⁽³⁾	[REDACTED]%	[REDACTED]%	[REDACTED]%

HISTORY AND CORPORATE STRUCTURE

	Pre-Series A Financing	Series A Financing	Series B Financing
Use of proceeds	We utilized the proceeds to (i) finance our R&D activities and (ii) fund our daily operations. As of the Latest Practicable Date, we had utilized all of the proceeds from the Pre-Series A Financing and Series A Financing and approximately 80% of proceeds from Series B Financing.		
Lock-up period	Pursuant to the applicable PRC law, within the 12 months following the [REDACTED], Shares issued by our Company prior to the [REDACTED] (including those held by the Pre-[REDACTED] Investors at the time of the [REDACTED]) are restricted from trading.		
Strategic benefits	At the time of the Pre-[REDACTED] Investments, our Directors were of the view that (i) our Company would benefit from the additional capital provided by the Pre-[REDACTED] Investors and their knowledge and experience; and (ii) the Pre-[REDACTED] Investments demonstrated the Pre-[REDACTED] Investors’ confidence in the operation and development of our Group. Leveraging the resources provided by the Pre-[REDACTED] Investors, we are able to bring in new business opportunities.		

Notes:

- (1) Excluding the amount of Shares subscribed by Kelun Pharmaceutical and the consideration paid by it under the Share Subscription by Kelun Pharmaceutical because Kelun Pharmaceutical is our promoter and we don’t regard Kelun Pharmaceutical as a pre-[REDACTED] investor of our Company. Please see “– Corporate History – Establishment and Major Shareholding Changes of Our Company – Series B Financing – Share Subscription by Kelun Pharmaceutical” above for the details of the Share Subscription by Kelun Pharmaceutical.
- (2) Post-money valuation is calculated on the basis of (a) cost per Share; and (b) the total number of Shares of our Company upon completion of the relevant round of the Pre-[REDACTED] investment. The corresponding valuation of our Company is calculated based on the proposed post-money capitalization of our Company at the time of the investments, and was determined based on, among other things, arm’s length negotiations between the relevant parties primarily taking into consideration the status and continuous development of our business and the progress in the R&D of our pipelines. The significant increase in valuation of our Company from the Pre-Series A Financing and the Series A Financing mainly reflects (i) the breakthroughs of our pipelines, including but not limited to, receiving the IND approval from the NMPA for the initiation of the global phase 1/2 clinical trial of SKB264 and the commencement of the pivotal phase 2 trial in China for A166 to treat advanced HER2+ BC; (ii) the industry-wide increased valuation of companies with similar pipelines; and (iii) the acquisition of our subsidiaries. The increase in valuation of our Company from the Series A Financing to the Series B Financing mainly reflects (i) the breakthroughs of our pipelines; including but not limited to, the commencement of the pivotal phase 3 trial in advanced TNBC patients for SKB264 and receiving IND approvals from the NMPA and FDA for a global phase 2 basket study of SKB264 in combination with Keytruda for selected advanced solid tumors; and (ii) our collaboration with first-tier multinational pharmaceutical companies, including but not limited to, granting to MSD an exclusive, royalty-bearing and sublicensable license to develop, use, manufacture and commercialize (1) our TROP2 ADCs, including SKB264, and products containing one or more such TROP2 ADCs outside Greater China; and (2) SKB 315, our CLDN18.2 ADC, and products based on SKB315 globally. Our anticipated market capitalization immediately upon completion of the [REDACTED] has primarily taken into account entering into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets for the treatment of cancer.
- (3) The [REDACTED] to the [REDACTED] is calculated based on the foreign exchange rate as of the Latest Practicable Date and the assumption that the [REDACTED] is HK\$[REDACTED] per [REDACTED] (being the [REDACTED] of the indicative [REDACTED] range).

HISTORY AND CORPORATE STRUCTURE

Information Relating to Our Pre-[REDACTED] Investors

Our Pre-[REDACTED] Investors include certain Sophisticated Investors, such as IDG Capital and SDIC, and each Sophisticated Investor has made meaningful investment in the Company at least six months before the [REDACTED]. To the best of the Company’s knowledge, information and belief and having made all reasonable enquiries, all the Pre-[REDACTED] Investors are Independent Third Parties. The background information of our Pre-[REDACTED] Investors as of the Latest Practicable Date is set out below.

Pre-[REDACTED] Investor	Background
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Ningbo Daoyi	Ningbo Daoyi is a limited liability company established under the laws of the PRC and primarily focuses on consulting. It is wholly owned by Li Jun (李軍), an Independent Third Party.
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Wealthy Linkage and Leyue Capital	Wealthy Linkage and Leyue Capital are companies incorporated in Hong Kong with limited liability and managed by IDG Capital. Each of Wealthy Linkage and Leyue Capital is ultimately controlled by Quan Zhou and Chi Sing Ho, each of whom is an Independent Third Party.
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Founded in 1992, IDG Capital is a pioneer in introducing foreign venture capital into China. During its over 30 years of operation, IDG Capital brings a powerful combination of global perspective and local experience to investment management, and its highly skilled team has an in-depth understanding of the China market with close relationships with many successful entrepreneurs and influential business leaders. IDG Capital’s clients include both international and Chinese institutional investors, such as foundations, public and private pension funds, sovereign wealth funds and family offices. IDG Capital funds invest primarily in TMT, advanced manufacturing, clean-tech and energy, consumer and entertainment, and healthcare sectors.

FIIF	FIIF is a limited partnership established under the laws of the PRC. It is managed by CS Capital Co., Ltd. (國投招商投資管理有限公司) (“CS Capital”). CS Capital is an equity investment management institution with investments in a range of industries. CS Capital and its affiliates had over RMB100 billion of assets under management. Its portfolio companies in biotech and healthcare sectors include, among others, Innovent Biologics, a company listed on the Stock Exchange (stock code: 1801), Ascentage Pharma, a company listed on the Stock Exchange (stock code: 6855), CanSino Biologics, a company listed on the Stock Exchange (stock code: 6185) and the Shanghai Stock Exchange (stock code: 688185), and Peijia Medical, a company listed on the Stock Exchange (stock code: 9996).
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HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED]

Investor

Background

FIIF has 36 limited partners, including the Ministry of Finance of the PRC (中華人民共和國財政部), National Council for Social Security Fund of the PRC (全國社會保障基金理事會), and State Development & Investment Corporation (國家開發投資集團有限公司) (a company wholly owned by the State-owned assets Supervision and Administration Commission of the State Council (國有資產監督管理委員會)). To the best knowledge of our Directors, each of the limited partners of FIIF is an Independent Third Party.

FIIF is a Sophisticated Investor.

LAV Kecheng and Suzhou Likang

LAV Kecheng is a company incorporated in Hong Kong with limited liability and primarily focuses on investment opportunities in biomedical and healthcare industry. LAV Kecheng is wholly owned by LAV Fund VI, L.P. and is ultimately controlled by Dr. Yi Shi, an Independent Third Party.

Suzhou Likang is a limited partnership incorporated under the laws of PRC and primarily focuses on the investments in healthcare area. The general partner of Suzhou Likang is Shanghai Liyi Investment Management Partnership (Limited Partnership) (上海禮貽投資管理合夥企業(有限合夥)) (“**Shanghai Liyi**”), which is ultimately controlled by Mr. Chen Fei (陳飛), an Independent Third Party.

As of the Latest Practicable Date, Suzhou Likang has 28 limited partners. China Pacific Life Insurance Co., Ltd. (中國太平洋人壽保險股份有限公司) (“**China Pacific Life**”) is the largest limited partner of Suzhou Likang, holding approximately 12.0% interest in Suzhou Likang. China Pacific Life is ultimately controlled by China Pacific Insurance (Group) Co., Ltd. (中國太平洋保險(集團)股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 601601), the London Stock Exchange (stock code: CPIC) and the Stock Exchange (stock code: 2601), an Independent Third Party. To the best knowledge of our Directors, each of the limited partners of Suzhou Likang is an Independent Third Party.

Each of LAV Kecheng and Suzhou Likang is an investment arm of Lilly Asia Ventures (the “**LAV**”). LAV is a leading Asia-based life science investment firm with portfolios covering all major sectors of the biomedical and healthcare industry including biopharmaceuticals, medical devices, diagnostics and healthcare services.

HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED]

Investor

Background

Gao Ling Liangheng is a limited partnership established under the laws of the PRC, the general partner of which is Shenzhen Gao Ling Tiancheng Phase III Investment Co., Ltd. (深圳高瓴天成三期投資有限公司) and the investment manager of which is Zhuhai Gao Ling Equity Investment Management Co., Ltd. (珠海高瓴股權投資管理有限公司), a limited liability company established in the PRC (“**Zhuhai Gao Ling**”). Zhuhai Gao Ling partners with exceptional entrepreneurs and management teams to create value, often with a focus on innovation and growth.

MSD

MSD is a limited liability company incorporated under the laws of New Jersey, the U.S. MSD is a wholly-owned subsidiary of Merck & Co., Inc. (“**Merck**”), a company listed on the New York Stock Exchange (stock code: MRK). Merck is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products and thus a Sophisticated Investor. From developing new therapies that treat and prevent disease to helping people in need, Merck is committed to improving health and well-being around the world. The principal business of MSD is the same as Merck.

Kexin Lunda and Cinda Capital

Kexin Lunda is a limited partnership established under the laws of the PRC, and primarily focuses on own funds investment. The general partner of Kexin Lunda is Cinda Capital which holds approximately 0.3% interest in Kexin Lunda.

The sole limited partner of Kexin Lunda is China Cinda Asset Management Co., Ltd. (中國信達資產管理股份有限公司) (“**China Cinda**”), a company listed on the Stock Exchange (Stock Code: 01359 and 04621 (preference shares)), holding approximately 99.7% interest in Kexin Lunda.

Cinda Capital, a limited liability company established under the laws of the PRC, is held as to 60.0% by Cinda Investment Company Limited (信達投資有限公司), a wholly-owned subsidiary of China Cinda, and 40.0% by Shenzhen Qianhai Huajian Equity Investment Company Limited (深圳市前海華建股權投資有限公司), which is also ultimately owned by China Cinda.

Cinda Capital primarily focuses on investment management. The beneficial owner of Kexin Lunda and Cinda Capital is China Cinda.

HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED]

Investor

Background

Anling Weijian

Anling Weijian is a limited partnership established under the laws of the PRC, and primarily focuses on equity investment. Hainan Zhumei Private Equity Fund Management Partnership (Limited Partnership) (海南鑄美私募基金管理合夥企業(有限合夥)) (“**Hainan Zhumei**”) is the general partner of Anling Weijian, holding 1.0% interest in Anling Weijian. The sole limited partner of Anling Weijian is Mao Benbing (毛本兵), an Independent Third Party, which holds 99.0% interest in Anling Weijian.

The general partner of Hainan Zhumei is Shanghai Zhumei Investment Management Co., Ltd. (上海鑄美投資管理有限公司), which is held as to 34.0%, 34.0% and 32.0% by Wang Siquan (汪私全), Yang Chongwei (楊崇偉) and Shanghai Weiquan Enterprise Management Consulting Partnership (Limited Partnership) (上海偉全企業管理諮詢合夥企業(有限合夥)) (“**Shanghai Weiquan**”), each of whom is an Independent Third Party. The general partner of Shanghai Weiquan is Yang Chongwei (楊崇偉).

Qingdao Quanze Investment Management Partnership (Limited Partnership) (青島全澤投資管理合夥企業(有限合伙)) (“**Qingdao Quanze**”) is the sole limited partner of Hainan Zhumei, holding approximately 83.2% interest in Hainan Zhumei. Yang Chongwei (楊崇偉), an Independent Third Party, is the general partner of Qingdao Quanze, holding approximately 41.8% interest in Qingdao Quanze. The other three individual Independent Third Parties hold together approximately 58.2% interest in Qingdao Quanze as its limited partners.

BOSC Xingling

BOSC Xingling is a limited partnership established under the laws of the PRC, and primarily focuses on equity investment. BOSC International Equity Investment Fund Management (Shenzhen) Co., Ltd (“**BOSC International Equity Investment**”) (上銀國際股權投資基金管理(深圳)有限公司) is the general partner of BOSC Xingling, holding approximately 0.3% interest in BOSC Xingling. BOSC International Equity Investment is wholly owned by BOSC International Consulting (Shenzhen) Co., Ltd. (上銀國際諮詢(深圳)有限公司), which is in turn wholly owned by BOSC International (Shenzhen) Co., Ltd. (上銀國際(深圳)有限公司) (“**BOSC International (Shenzhen)**”). Shanghai International (Shenzhen) is wholly owned by Bank of Shanghai (上海銀行), a company listed on the Shanghai Stock Exchange (stock code: 601229), an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED]

Investor

Background

BOSC Xingling has 14 independent limited partners including 13 individual limited partners, with Guo Qin (郭勤) being its largest limited partner, holding approximately 19.7% interest in BOSC Xingling, Zhang Wenhao (張文豪) holding approximately 12.3% interest in BOSC Xingling, each of Guo Chuhua (郭楚華) and Wu Yuwei (吳裕偉) holding approximately 11.5% interest in BOSC Xingling and other ten individual limited partners in together holding approximately 45.0% interest in BOSC Xingling. One remaining limited partner of BOSC Xingling is Shenzhen Dehaiwei Investment Holding Co., Ltd. (深圳市德海威投資控股有限公司), which is held as to 99.0% by Shenzhen Weiyang Venture Capital Partnership (Limited Partnership) (深圳市威揚創業投資合夥企業(有限合夥)) (“**Shenzhen Weiyang**”). Each of Zhang Yongfeng (張永峰) and Zhang Yonggang (張永剛), an Independent Third Party, is the sole general partner and sole limited partner of Shenzhen Weiyang, with each holding 95.0% and 5.0% interest in Shenzhen Weiyang, respectively.

Gygnus Real

Gygnus Real is a limited company incorporated in the British Virgin Islands and is wholly-owned by Sherpa Healthcare Fund II, L.P., which is controlled by CAI Daqing. Gygnus Real and its affiliates are Sophisticated Investors specializing in investments in the healthcare sector.

HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED]

Investor

Background

Chengdu Wenjiang
Emerging
Industry Venture
and Wutong Juke

Chengdu Wenjiang Emerging Industry Venture is a limited partnership established under the laws of the PRC and primarily focuses on equity investment. Chengdu Guanghua Wutong Equity Investment Fund Management Co., Ltd. (成都光華梧桐股權投資基金管理有限公司) (“**Guanghua Wutong**”) is the general partner of Chengdu Wenjiang Emerging Industry Venture, holding approximately 1.2% interest in Chengdu Wenjiang Emerging Industry Venture. Guanghua Wutong is ultimately wholly owned by the Bureau of State-owned Assets Supervision and Administration of Wenjiang District of Chengdu (成都市溫江區國有資產監督管理局) (“**Wenjiang SASAC**”). Chengdu Major Industrialisation Projects Equity Investment Partnership (Limited Partnership) (成都溫江重大產業化項目股權投資基金合夥企業(有限合夥)) (“**Major Industrialisation Projects Fund**”) is the sole limited partner of Chengdu Wenjiang Emerging Industry Venture, holding approximately 98.8% interest in Chengdu Wenjiang Emerging Industry Venture. Guanghua Wutong is the general partner of Major Industrialisation Project Fund, and the Chengdu Wenjiang Xinrongxi City Operation Group Limited (成都溫江興蓉西城市運營集團有限公司), a company wholly owned by the Wenjiang SASAC, is the largest limited partner holding approximately 60.0% interest in Major Industrialisation Projects Fund.

Wutong Juke is a limited partnership established under the laws of the PRC, and primarily focuses on equity investment. Mr. Wang Fei (王飛), an Independent Third Party, is the general partner of Wutong Juke, holding approximately 0.2% interest in Wutong Juke. Chengdu Wenjiang Emerging Industry Venture is the largest limited partner of Wutong Juke, holding approximately 97.3% interest in Wutong Juke.

Therefore, the beneficial owner of Chengdu Wenjiang Emerging Industry Venture and Wutong Juke is Wenjiang SASAC.

HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED]

Investor

Background

Yunqi Xinneng and
ZHOU Youcai

Yunqi Xinneng is a limited partnership established under the laws of the PRC and primarily focuses on consulting and investment. Shenzhen Yunqi Private Equity Investment Fund Management Co., Ltd (深圳雲起私募股權投資基金管理有限公司) (“**Yunqi Private Equity Investment**”) is the general partner of Yunqi Xinneng. Mr. ZHOU Youcai (周有財), an Independent Third Party, is the sole limited partner of Yunqi Xinneng holding approximately 99.95% interest in Yunqi Xinneng. Yunqi Private Equity Investment, a company incorporated under the laws of the PRC, is wholly owned by Shenzhen Congling Investment Company Limited (深圳蔥嶺投資有限公司) (“**Shenzhen Congling**”). Tong Shanbing (童善炳), an Independent Third Party, being the largest shareholder of Shenzhen Congling, holds 60.0% interest in Shenzhen Congling.

Longyi Technology

Longyi Technology a limited company established under the laws of the PRC and primarily focuses on the wholesale of traditional Chinese and western medical products. It is owned as to 70% by Mr. Li Baiting (李柏廷) and 30% by Ms. Yang Lu (楊路), both of whom are Independent Third Parties of the Company.

Special Rights of the Pre-[REDACTED] Investors

Pursuant to the shareholders’ agreement entered into by our Shareholders dated January 3, 2023, the Pre-[REDACTED] Investors were granted certain special rights, including, amongst others, redemption right, preemptive right, right of first refusal, co-sale right, liquidation preference and anti-dilution right. All these special rights had been terminated upon the submission of the application by our Company to the CSRC for the [REDACTED] and [REDACTED] on February 15, 2023. The above special rights shall be resumed if (i) the [REDACTED] fails to be consummated with twelve (12) months from February 15, 2023 or (ii) the Company voluntarily withdraws the application for the [REDACTED] and [REDACTED].

Compliance with Interim Guidance and Guidance Letters

On the basis that (i) the consideration for Pre-Series A Financing and Series A Financing was settled more than 28 clear days before the date of first submission of the [REDACTED] application to the Stock Exchange; (ii) the consideration for Series B Financing was settled no less than 120 clear days before the [REDACTED]; and (iii) the special rights granted to the Pre-[REDACTED] Investors had been terminated upon the submission to the CSRC of the [REDACTED] application for the [REDACTED], the Joint Sponsors confirm that the Pre-[REDACTED] Investments are in compliance with the Interim Guidance on Pre-[REDACTED] Investments (HKEx-GL29-12) issued on January 2012 and updated in March 2017 by the Stock Exchange and the Guidance on Pre-[REDACTED] Investments (HKEx-GL43-12) issued on October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange.

HISTORY AND CORPORATE STRUCTURE

Public Float

Following the completion of the [REDACTED], 149,589,850 Domestic Shares held by existing domestic Shareholders and 5,548,478 Unlisted Foreign Shares held by existing foreign Shareholders will not be converted into H Shares and [REDACTED], and thus will not be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules. For details of the conversion of our Domestic Shares and Unlisted Foreign Shares into H Shares before the [REDACTED], see “– Shareholding Structure of our Company as at the [REDACTED]” below.

Since the Employee Incentive Platforms are close associates of our Controlling Shareholder and therefore are core connected persons of our Company, 9,000,000 H Shares to be converted from Domestic Shares held by the Employee Incentive Platforms will not be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules upon the [REDACTED]. As Dr. WANG Jingyi is a Director of our Company, the 2,850,000 H Shares to be converted from Domestic Shares held by him will not be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules upon the [REDACTED].

Save as disclosed above, to the best of our Director’s knowledge, no other Shareholders (i) is a core connected person of the Group; (ii) has been financed directly or indirectly by a core connected person of the Group for the [REDACTED] of Shares; or (iii) is accustomed to take instructions from a core connected person of the Group in relation to the acquisition, disposal, voting or other disposition of the Shares registered in his/her/its name or otherwise held by him/her/it.

According to the applicable PRC Laws, within 12 months after the [REDACTED], all existing Shareholders of our Company will not be able to sell any share held by them.

Immediately upon completion of the [REDACTED], assuming that (i) [REDACTED] H Shares are issued to the public Shareholders in the [REDACTED]; (ii) the [REDACTED] is not exercised; (iii) 19,620,539 Domestic Shares and 18,623,632 Unlisted Foreign Shares will be converted to H Shares; (iv) based on an [REDACTED] of HK\$[REDACTED] per H Share (being the [REDACTED] of the indicative [REDACTED] range), an aggregate of [REDACTED] H Shares representing approximately [REDACTED]% of our [REDACTED] with a [REDACTED] of substantially over HK\$375 million will be held by the public in accordance with 8.08(1)(a) and 18A.07 of the Listing Rules. As a result, over 25% of our Company’s total issued Shares with a [REDACTED] of substantially over HK\$375 million will be held by the public upon completion of the [REDACTED] in accordance with Rules 8.08(1)(a) and 18A.07 of the Listing Rules.

HISTORY AND CORPORATE STRUCTURE

ACQUISITIONS, MERGERS AND DISPOSALS

We have not conducted any acquisitions, disposals or mergers during the Track Record Period and up to the Latest Practicable Date that we consider to be material to us.

SPIN-OFF

Kelun Pharmaceutical, our Controlling Shareholder, is a company listed in the PRC. The [REDACTED] of our Company constitutes a spin-off from a domestic listed company (the “Spin-Off”) as defined under the Spin-off Rules. The Spin-Off has been approved by the shareholders of Kelun Pharmaceutical at an extraordinary general meeting held on January 30, 2023. Kelun Pharmaceutical filed the relevant announcements related to the Spin-Off with the Shenzhen Stock Exchange on January 14, 2023.

REASON FOR THE [REDACTED]

Our Company is seeking a [REDACTED] of its H Shares on the Stock Exchange in order to provide further capital for its R&D, manufacturing and commercialization of innovative therapies to address medical needs in China and globally, as described in more details in “Future Plans and [REDACTED]” in this document.

SHAREHOLDING STRUCTURE OF OUR COMPANY AS AT THE [REDACTED]

Insofar as our Directors are aware, immediately following the completion of the [REDACTED] and Conversion of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised), the following table sets forth the details of the Shares to be held by our Shareholders as at the [REDACTED]:

Shareholder	Description of Shares	Number	Percentage in our total issued share capital
<i>Controlling Shareholders</i>			
Kelun Pharmaceutical	Domestic Shares	115,555,685	[REDACTED]%
<i>Employee Incentive Platforms</i>			
Kelun Huicai	Domestic Shares	5,250,000	[REDACTED]%
	H Shares converted from Domestic Shares	2,250,000	[REDACTED]%
Kelun Huineng	Domestic Shares	5,250,000	[REDACTED]%
	H Shares converted from Domestic Shares	2,250,000	[REDACTED]%

HISTORY AND CORPORATE STRUCTURE

Shareholder	Description of Shares	Number	Percentage in our total issued share capital
Kelun Huizhi	Domestic Shares	5,250,000	[REDACTED]%
	H Shares converted from Domestic Shares	2,250,000	[REDACTED]%
Kelun Huide	Domestic Shares	5,250,000	[REDACTED]%
	H Shares converted from Domestic Shares	2,250,000	[REDACTED]%
<i>Director</i>			
WANG Jingyi	Domestic Shares	2,850,000	[REDACTED]%
	H Shares converted from Domestic Shares	2,850,000	[REDACTED]%
<i>Pre-[REDACTED] investors</i>			
MSD	H Shares converted from Unlisted Foreign Shares	13,443,693	[REDACTED]%
Wealthy Linkage ⁽¹⁾	Unlisted Foreign Shares	3,633,914	[REDACTED]%
	H Shares converted from Unlisted Foreign Shares	3,633,914	[REDACTED]%
Leyue Capital ⁽¹⁾	Unlisted Foreign Shares	1,008,276	[REDACTED]%
	H Shares converted from Unlisted Foreign Shares	1,008,277	[REDACTED]%
FIIF	Domestic Shares	7,144,177	[REDACTED]%
Ningbo Daoyi	H Shares converted from Domestic Shares	4,200,000	[REDACTED]%
Kexin Lunda ⁽²⁾	Domestic Shares	1,160,506	[REDACTED]%
	H Shares converted from Domestic Shares	1,160,506	[REDACTED]%
Cinda Capital ⁽²⁾	H Shares converted from Domestic Shares	386,835	[REDACTED]%
LAV Kecheng ⁽³⁾	Unlisted Foreign Shares	771,852	[REDACTED]%
Suzhou Likang ⁽³⁾	Domestic Shares	385,926	[REDACTED]%
Anling Weijian	Domestic Shares	967,088	[REDACTED]%
BOSC Xingling	H Shares converted from Domestic Shares	734,987	[REDACTED]%
Gygnus Real	Unlisted Foreign Shares	134,436	[REDACTED]%
	H Shares converted from Unlisted Foreign Shares	537,748	[REDACTED]%

HISTORY AND CORPORATE STRUCTURE

Shareholder	Description of Shares	Number	Percentage in our total issued share capital
Wutong Juke ⁽⁴⁾	Domestic Shares	410,690	[REDACTED]%
	H Shares converted from Domestic Shares	205,345	[REDACTED]%
Chengdu Wenjiang Emerging Industry Venture ⁽⁴⁾	H Shares converted from Domestic Shares	386,835	[REDACTED]%
ZHOU Youcai	H Shares converted from Domestic Shares	386,835	[REDACTED]%
Gao Ling Liangheng	Domestic Shares	115,778	[REDACTED]%
	H Shares converted from Domestic Shares	115,778	[REDACTED]%
Longyi Technology	H Shares converted from Domestic Shares	193,418	[REDACTED]%
Others			
Other [REDACTED]	H Shares issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	Domestic Shares	149,589,850	[REDACTED]%
	Unlisted Foreign Shares	5,548,478	[REDACTED]%
	H Shares	[REDACTED]	[REDACTED]%
Total		<u>[REDACTED]</u>	<u>100.00%</u>

Notes:

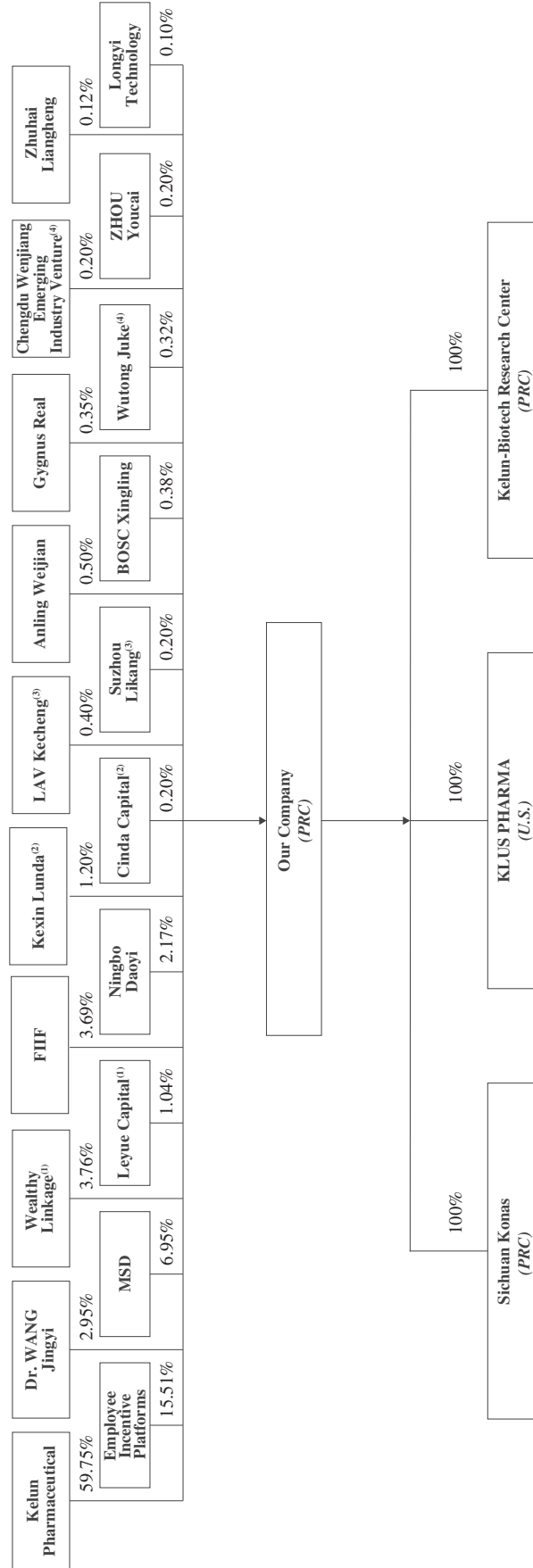
- (1) Wealthy Linkage and Leyue Capital are companies managed by IDG Capital. For more details on Wealthy Linkage and Leyue Capital, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (2) The beneficial owner of Kexin Lunda and Cinda Capital is China Cinda Asset Management Co., Ltd. (Stock Code: 01359 and 04621 (preference shares)). For more details on Kexin Lunda and Cinda Capital, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (3) Each of LAV Kecheng and Suzhou Likang is a investment arm of Lilly Asia Ventures. For more details on LAV Kecheng and Suzhou Likang, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (4) The beneficial owner of Chengdu Wenjiang Emerging Industry Venture and Wutong Juke is Bureau of State-owned Assets Supervision and Administration of Wenjiang District of Chengdu (成都市溫江區國有資產監督管理局). For more details on Chengdu Wenjiang Emerging Industry Venture and Wutong Juke, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.

HISTORY AND CORPORATE STRUCTURE

OUR SHAREHOLDING AND CORPORATE STRUCTURE

Immediately Prior to the [REDACTED]

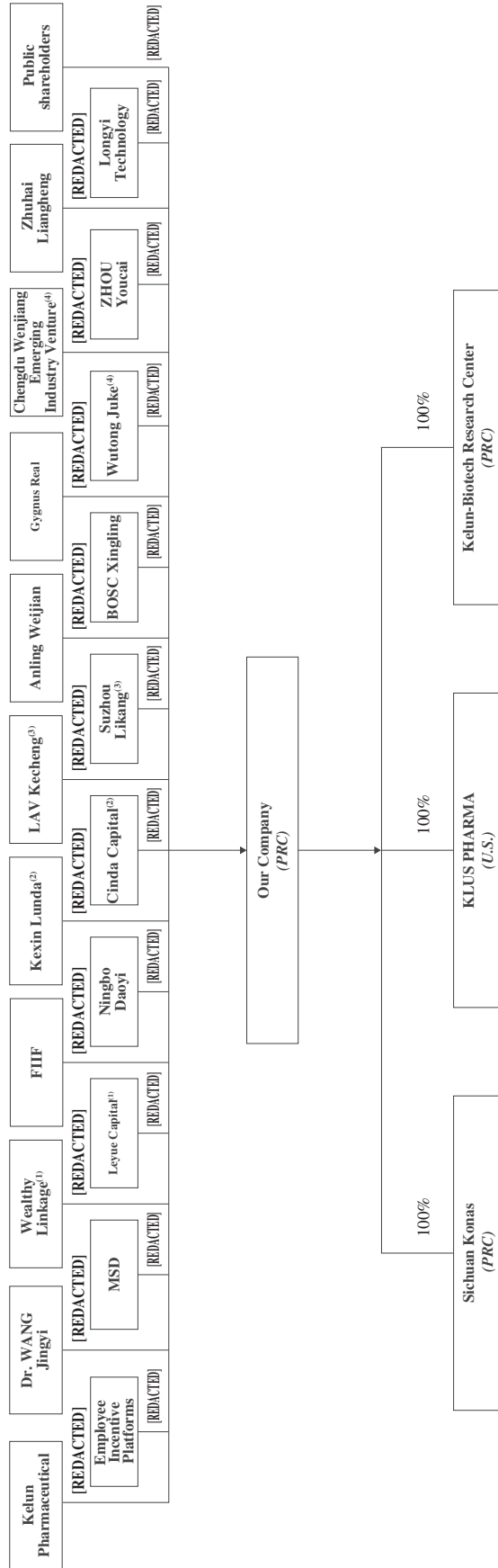
Our corporate and shareholding structure immediately prior to the completion of the [REDACTED] is as follows:



HISTORY AND CORPORATE STRUCTURE

Immediately Following the [REDACTED]

The following chart sets forth our corporate and shareholding structure upon the completion of the [REDACTED], assuming the [REDACTED] is not exercised:



Notes:

- (1) Wealthy Linkage and Leyue Capital are companies managed by IDG Capital. For more details on Wealthy Linkage and Leyue Capital, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (2) The beneficial owner of Kexin Lunda and Cinda Capital is China Cinda Asset Management Co., Ltd. (Stock Code: 01359 and 04621 (preference shares)). For more details on Kexin Lunda and Cinda Capital, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
- (3) Each of LAV Kecheng and Suzhou Likang is a investment arm of Lilly Asia Ventures. For more details on LAV Kecheng and Suzhou Likang, see “– Pre-[REDACTED] Investments – Information Relating to Our Pre-[REDACTED] Investors”.
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BUSINESS

OVERVIEW

We are an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally. Empowered by our integrated drug development capabilities and a well-established management system that covers all key business functionalities, we are dedicated to the in-house development of differentiated treatments to improve the existing standard of care. Notably, we are one of the first movers and a leading developer of antibody drug conjugates (ADCs), with over a decade of accumulated experience in ADC development. We are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an integrated ADC platform, *OptiDC*.

We take a systematic, indication-oriented approach to target the world’s prevalent or hard-to-treat cancers, and other diseases and conditions affecting a large and underserved population. Over the years, we have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization, which empower us to rapidly and strategically advance a differentiated and clinically valuable pipeline of 33 assets, including 14 in clinical stage as of the Latest Practicable Date. Supported by three in-house developed technology platforms with proprietary know-how in ADCs, biologics (monoclonal antibodies (mAbs) and bispecific antibodies (bsAbs)) and small molecule drugs and validated by our clinical-stage drug candidates, our pipeline is diverse and synergistic in drug modalities, mechanisms, and indication coverage. Our drug development capabilities are further bolstered by current good manufacturing practice (cGMP)-compliant, end-to-end manufacturing capabilities and a comprehensive quality control system. Furthermore, we are well-positioned to expand our commercialization infrastructure and market access, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network.

The clinical value of our pipeline and our drug development capabilities are recognized by the strategic partnerships we have forged worldwide to unlock the global market potential of key assets. To date, we have entered into nine out-license agreements, including three license and collaboration agreements with Merck Sharp & Dohme LLC (together with its affiliates, “MSD”) to develop up to nine ADC assets for cancer treatment with upfront and milestone payments totaling up to US\$11.8 billion. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical MNC. Our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world’s largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth.

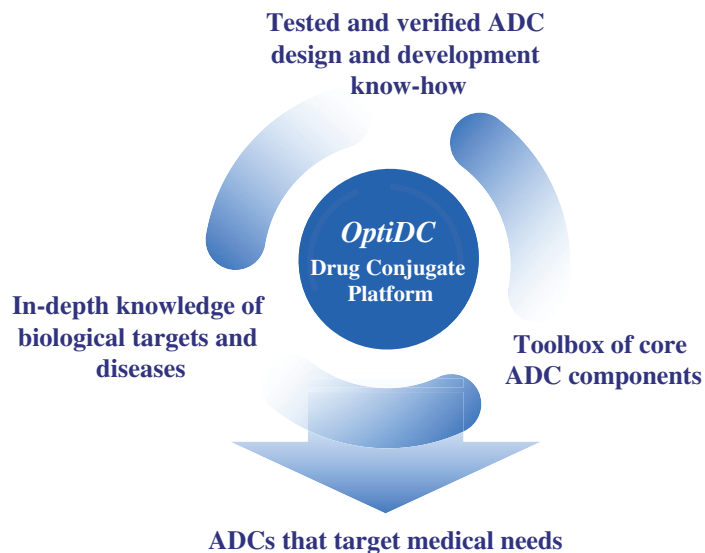
BUSINESS

Going forward, we strive to advance our pipeline towards commercialization and enhance our integrated drug development capabilities. We will continue to lead the R&D and clinical activities of our drug candidates, including, for assets out-licensed to our strategic partners, in the regions where we retain the rights to their development and commercialization. In addition, we are dedicated to optimizing our R&D platforms and developing novel technologies to support the R&D of innovative drugs. We will also continue to expand our cGMP manufacturing and quality control facilities, and enhance our in-house commercialization functionalities, to support the future launch of our pipeline assets and our goal to become a leading global biopharmaceutical company.

Our Technology Platforms

We have established three core platforms specializing in ADC, biologics and small molecule technologies that serve as the foundation of our discovery and development of innovative medicines for medical needs in selected disease areas, such as oncology, autoimmune diseases and metabolic diseases. These platforms cover the entire R&D process for different drug modalities and are integrated to allow cross-functional synergies at crucial stages of drug development.

- **ADC Platform.** We are one of the first movers and a leading developer of ADCs, with over a decade of accumulated experience in ADC development. According to Frost & Sullivan, we are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an integrated ADC development platform, which supports our systematic development of ADCs across their entire lifecycle. Our ADC platform, *OptiDC*, is supported by three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified ADC design and development know-how, and a toolbox of core ADC components. Through over a decade of development, we have developed a toolbox of core ADC components which gives us the versatility to engineer customized ADCs optimized for different biological targets to address medical needs in a broad range of indications. We have honed our expertise in ADC process development, manufacturing and quality control, which we believe is crucial in bringing our ADCs from bench to bedside. Notably, our ADC platform is tested and verified through preclinical studies and clinical trials with over 1,160 patients as of the Latest Practicable Date.



BUSINESS

Our platform has been tested through extensive studies and trials, including validation from over ten clinical or preclinical ADC candidates. Our ADC design strategies are exemplified by *Kthiol*, our proprietary drug-linker strategy implemented in SKB264. An optimized balance between safety and efficacy is achieved in this strategy by incorporating a novel irreversible antibody conjugating technology, a pH-sensitive toxin release mechanism, and a moderately potent toxin homogeneously loaded with DAR 7.4. Our continued advancement in ADC research and development forms a feedback loop that strengthens our platform, and enables our consistent and rapid delivery of highly competitive ADC candidates.

- **Biologics Platform.** Our extensive biologics technology platform, while complementing our ADC platform, serves as the foundation of our immunotherapy and targeted therapy franchises. This platform is focused on mAbs and bsAbs and possesses end-to-end antibody development capabilities ranging from antibody discovery and optimization to bioprocessing and scale-up manufacturing. As of the Latest Practicable Date, we had six clinical assets and various preclinical assets developed under our biologics platform. Our clinical assets include two mAbs at pivotal phase 3 or NDA registration-stage, A167 (PD-L1) and A140 (EGFR), as well as SKB337 (PD-L1/CTLA4), A289 (LAG3), SKB378 (TSLP) and SKB336 (FXI/FXIa). Our preclinical assets are mainly antibodies with novel targets and differentiated mechanisms of action that potentially enable broad clinical applications and reduced drug resistance.
- **Small Molecule Platform.** Our small molecule platform is driven by the integration of medicinal chemistry and computer-aided drug design (CADD) technologies, such as molecular docking, pharmacophore modeling, virtual screening and absorption, distribution, metabolism, elimination and toxicity (ADMET) prediction. These capabilities allow us to focus on compound optimization in early-stage research, which help rationalize and accelerate our preclinical drug discovery. Leveraging this platform, we have built an innovative pipeline of four clinical-stage small molecule drug candidates, including A400 (selective RET inhibitor), A223 (JAK1/2 inhibitor), A296 (STING agonist) and A277 (KOR agonist), and various preclinical assets. We are also exploring state-of-the-art technologies such as proteolysis targeting chimera (PROTAC) to navigate challenging protein targets, with one small-molecule PROTAC candidate currently at IND-enabling stage.

Our Pipeline

Our pipeline targets the world’s prevalent or hard-to-treat cancers, such as breast cancer (BC), non-small cell lung cancer (NSCLC), gastrointestinal (GI) cancers (including gastric cancer (GC) and colorectal cancer (CRC)), as well as non-oncology diseases and conditions affecting a large and underserved population. As of the Latest Practicable Date, we had established a pipeline of 14 clinical-stage drug candidates, including five in pivotal trial- or NDA registration-stage. We have also assembled a diverse portfolio of preclinical assets, including four in IND-enabling stage, to further enrich our expanding pipeline targeting medical needs. The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets.

BUSINESS

Our oncology franchise features diversified treatment modalities and targets different mechanisms to comprehensively treat prevalent or hard-to-treat cancers in China and worldwide, anchored by the following assets:

- **SKB264 (*sacituzumab tirumotecan*)**, one of our Core Products, is a novel TROP2 ADC targeting advanced solid tumors. Drugs that successfully target TROP2 have vast market potential as TROP2 is frequently overexpressed across a broad spectrum of cancers, especially in highly prevalent or hard-to-treat cancers such as BC, NSCLC, GC and OC. The global TROP2 ADC market is expected to increase from US\$0.7 billion in 2022 to US\$25.9 billion by 2030, representing a CAGR of 57.6%, while the TROP2 ADC market in China, following the NMPA approval of the first TROP2 ADC in June 2022, is projected to grow from RMB0.2 billion in 2023 to RMB23.6 billion by 2030 at a CAGR of 103.0%.

Positioned to be the first domestically developed TROP2 ADC in China, SKB264 utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window. Preliminary clinical data from SKB264’s global phase 1/2 trial showed that SKB264 demonstrated encouraging ORRs across multiple types of heavily pretreated advanced solid tumors, highlighted by an ORR of 43.6%, 42.9% and 43.6% in heavily pre-treated TNBC, HR+/HER2- BC and NSCLC patients, respectively. SKB264 also demonstrated a potentially favorable safety profile. Based on non-head-to-head cross-trial comparisons, SKB264 demonstrated lower incidences of decreased neutrophil count (54% vs 78% for all grades, 26% vs 49% for \geq grade 3) and diarrhea (4% vs 59% for all grades, 0% vs 11% for \geq grade 3) compared with Trodelvy; and no incidence of treatment-related interstitial lung disease (ILD) compared with that reported in DS-1062-treated patients (6% for all grades and 2% for \geq grade 3). We are also exploring SKB264’s early-line potential in combination therapy. Based on preliminary results from a phase 2 trial conducted in China, SKB264 in combination with A167 demonstrating a promising ORR of 85.7% as a first-line therapy in advanced TNBC patients.

Supported by its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 outside Greater China. See “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB264” for details.

We are actively advancing a multi-strategy clinical development plan to explore SKB264’s potential as a monotherapy and combination therapies to treat various advanced solid tumors, including BC, NSCLC and other major cancers. For details, see “– Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan.”

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- **A166 (*trastuzumab botidotin*)**, another Core Product, is a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors. It is positioned to target multiple cancer indications with high prevalence and medical needs, with the potential to be one of the first domestically developed ADCs for HER2-positive (HER2+) BC in China. HER2 overexpression is widely recognized as a major driver of prevalent cancers, including BC and GI cancers.

Configured with a potent cytotoxic payload, clinically proven mAb and site-specific conjugation technology, A166 demonstrated promising efficacy in heavily pre-treated advanced HER2+ BC patients with an ORR of 73.9% at RP2D and in advanced HER2+ GC patients with an ORR of 31.3%, based on preliminary results from our ongoing phase 1 dose expansion study and ongoing phase 1b trial in China. A166 also showed a differentiated safety profile from that of Kadcyła, Enhertu and Aidixi, the only three FDA and/or NMPA-approved HER2 ADCs as of the Latest Practicable Date, with lower incidence of haematological, GI and lung toxicities in non-head-to-head, cross-trial comparisons. Although A166 demonstrated higher incidences of ocular and peripheral nerve-related toxicities, they were reversible and generally manageable. A166 has met the primary endpoints of its pivotal phase 2 trial for advanced HER2+ BC based on results from the primary analysis, which we used to submit an NDA to the NMPA in May 2023. In addition to our pivotal phase 2 trial for advanced HER2+ BC, we are exploring the therapeutic potential of A166 in multiple ongoing phase 1b clinical trials in China for other advanced HER2+ solid tumors, including GC and CRC.

- **SKB315** is a novel CLDN18.2 ADC targeting advanced solid tumors. As of the Latest Practicable Date, there were no CLDN18.2-targeting therapies approved globally. Due to its selective expression in prevalent and lethal cancers that have limited effective treatments such as GC and PC, CLDN18.2 has been a promising target pursued by multiple biopharmaceutical and biotech companies for in-house development and licensing deals. In June 2022, we out-licensed the global development and commercialization rights for SKB315, currently in phase 1a clinical trial, to MSD. With a differentiated payload-linker design and an in-house developed humanized CLDN18.2 antibody, SKB315 demonstrated encouraging efficacy and safety across various preclinical *in vivo* tumor models with heterogeneous CLDN18.2 expression, indicating its promising therapeutic potential.
- **A167 (*tagitanlimab*)**, our PD-L1 mAb, is expected to be our first commercialized product and the backbone of our immunotherapy franchise, with an NDA submitted to the NMPA for recurrent or metastatic nasopharyngeal carcinoma (RM-NPC) in November 2021 and conditional marketing approval expected in the second half of 2023 or the first half of 2024. We are actively exploring A167’s potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise, beginning with two ongoing phase 2 trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC.

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- **A140**, a pivotal phase 3 biosimilar of EGFR mAb cetuximab. A140 has potential to be the first cetuximab biosimilar in China with an anticipated NDA filing in the second half of 2023, providing increased accessibility and affordability for a widely used therapeutic targeting a key pathway in many cancers, starting with rat sarcoma virus (RAS) wild-type mCRC, recurrent and/or metastatic HNSCC (RM-HNSCC) and locally advanced HNSCC (LA-HNSCC). A140 demonstrated pharmacokinetic (PK) equivalence to cetuximab in a phase 1 trial, with clinical equivalence being evaluated in a pivotal phase 3 trial.
- **A400**, a phase 1/2-stage second-generation selective RET inhibitor, is positioned to be the first domestically developed selective RET inhibitor for NSCLC, medullary thyroid cancer (MTC) and other solid tumors with a high prevalence of RET alterations. We have designed A400 with a novel proprietary molecular structure to potentially address selective RET inhibitor resistance while maintaining target selectivity, efficacy and safety with reduced manufacturing cost and difficulty. Based on preliminary results from its ongoing phase 1/2 trial, A400 demonstrated promising anti-tumor efficacy in patients with advanced RET+ solid tumors, highlighted by ORR of 74% and 66.7% at RP2D for 1L and 2L+ advanced RET+ NSCLC, respectively. Notably, A400 also demonstrated therapeutic potential in selective RET inhibitor-resistant patients with an ORR of 33% and DCR of 83% at RP2D, as well as a potentially favorable safety profile differentiated from approved first-generation selective RET inhibitors. In March 2021, we granted to Ellipses, a U.K.-based international drug development company, an exclusive license to develop, manufacture and commercialize A400 outside Greater China and certain Asian countries.

We will also continue to accelerate the R&D of our preclinical oncology assets. For example, we are developing over ten preclinical ADC assets with their respective targets expressed across a broad spectrum of solid tumors. See “– Our Pipeline – Oncology Franchise – ADCs – Preclinical ADC Assets.” for further details. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau. For details, see “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets.”

Our non-oncology franchise covers a range of diseases and conditions with large patient populations and medical needs, with a primary focus on immune-mediated diseases, including rheumatoid arthritis (RA) and alopecia areata (AA). Our non-oncology franchise is headlined by A223, potentially one of the first small molecule JAK1/2 inhibitors developed domestically for multiple autoimmune diseases with large patient populations, including RA and AA, in China. A223 has demonstrated an encouraging safety profile in three completed trials and two ongoing trials, where most TEAEs were mild or moderate with no incidence of black box

BUSINESS

warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated promising anti-rheumatic efficacy in moderate-to-severe RA patients, with A223 2 mg achieving substantial and statistically significant ACR20 and ACR50 differences at week 12 compared with placebo. Notably, based on non-head-to-head comparison, the ACR20 and ACR50 differences achieved by A223 2 mg are greater than those of Olumiant 4 mg, the approved dosage of Olumiant in China, in Chinese patients with moderate-to-severe RA. These promising clinical results indicates the potential of A223 to be an effective treatment option with improved efficacy and safety for RA. Besides RA, A223 also target AA, a common autoimmune disease that affected approximately 4.0 million people in China in 2022.

In addition to A223, we are also evaluating three other clinical-stage assets (A277, SKB378 and SKB336) and various preclinical assets to target indications ranging from chronic kidney disease (CKD)-associated pruritus (CKD-aP), moderate-to-severe asthma, thromboembolic disorders, to other diseases and conditions with large patient populations and medical needs. Apart from our existing assets, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

Our Integrated Drug Development Capabilities

We have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization. Our drug development capabilities are governed by a well-established management system that covers all key business functionalities, which provides a framework for our internal teams to engage in constructive dialogue and evaluation, particularly when making critical decisions for each drug development plan. Meanwhile, we implement a dynamic global business development strategy to maximize the commercial value of our pipeline in major international markets, leveraging our experience in forging strategic partnerships worldwide.

Our in-house R&D capabilities, built on three technology platforms, give us control and visibility over our R&D process, reduces our reliance on CROs and enable us to ensure the quality and efficiency of our drug development programs. Our drug development capabilities are further bolstered by cGMP-compliant, end-to-end manufacturing capabilities that cover the entire development lifecycle of ADCs, including two 2,000 litre (L) single-use bioreactors, one 300 L ADC conjugation tank with a maximum annual production capacity of 40 batches of ADC drug substance and facilities for payload-linker synthesis, antibody formulation and ADC formulation, as well as a comprehensive quality control system. We are building up our commercialization infrastructure in anticipation of our late-stage drug candidates’ commercial launch in China, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network.

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Our drug development capabilities are recognized by the breadth, depth and commercial value of the strategic partnerships we have forged worldwide, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. These landmark transactions speak to the quality and soundness of our capabilities in every key step of our ADC development process, from drug discovery to manufacturing and quality control.

OUR COMPETITIVE STRENGTHS

Integrated ADC development platform, “*OptiDC*,” with a competitive ADC drug portfolio to address medical needs globally

We are one of the first movers and a leading developer of ADCs, with over a decade of accumulated experience in ADC development. According to Frost & Sullivan, we are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an integrated ADC development platform, *OptiDC*, which supports our systematic development of ADCs across their entire lifecycle. Our ADC platform is the engine for our continued innovation, and has been validated by our deep ADC drug portfolio of over ten clinical and preclinical assets.

ADCs have become one of the fastest-growing treatment modalities for cancer in recent years. Combining the target selectivity of antibodies and the cell-killing potency of cytotoxic drugs, ADCs are designed to utilize an antibody to deliver cytotoxic drugs selectively to tumor cells, potentially reducing the significant off-target toxicity associated with classic chemotherapy while using highly potent cytotoxic drugs, thereby leading to improved therapeutic window and efficacy. ADCs have presented a major scientific challenge to researchers due to the high degree of technological sophistication required to design and produce a balanced drug. Only recently have ADCs begun to gain momentum, with a total of 12 FDA-approved ADCs to date, including Enhertu (HER2-directed) and Padcev (Nectin-4-directed) in 2019 and Trodelvy (TROP2-directed) in 2020 for the treatment of solid tumors. ADCs have progressed from a late-line treatment in selected blood cancers to a promising early-line therapeutic modality for broader solid tumor indications and beyond. Globally, the ADC market is expected to grow at a 30.0% CAGR from approximately US\$7.9 billion in 2022 to approximately US\$64.7 billion by 2030. In China, the ADC market is expected to grow at a 72.8% CAGR from approximately RMB0.4 billion in 2022 to about RMB66.2 billion by 2030.

Through over a decade of development, we have established an integrated ADC development platform, *OptiDC*, with three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified ADC design and development know-how, and a toolbox of core ADC components. Through over a decade of development, we have developed a toolbox of core ADC components, which gives us the versatility to engineer customized ADCs optimized for different biological targets to address medical needs in a broad range of indications. We have honed our expertise in ADC process development, manufacturing and quality control, which we believe is crucial in bringing our ADCs from bench to bedside. These technologies and capabilities are the backbone of our integrated ADC development platform, which is protected by over 40 patents and patent applications globally, and form our strategic moat against competition.

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We have entered into three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment, with upfront and milestone payments totaling up to US\$11.8 billion. MSD is a global health care company that delivers innovative health solutions. In recent years, MSD has continued to seek strategic business development opportunities to augment its robust internal pipeline, including through collaboration with us to strengthen its ADC portfolio. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical MNC. Notably, our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world’s largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. These landmark transactions speak to the quality and soundness of our capabilities in every key step of the ADC development process, from drug discovery to manufacturing and quality control.

Equipped with deep expertise in this field, we are well positioned to further explore new frontiers of ADC technology to address medical needs. We are establishing novel ADC designs to further advance our ADC portfolio via a multi-pronged strategy, including (i) further optimizing our payload/linker technologies to solidify our ADC capabilities; (ii) developing bispecific ADCs (bsADCs) equipped with dual-targeting antibodies to deliver enhanced clinical benefits; (iii) developing other novel ADC designs such as immunostimulatory ADCs (iADCs), radionuclide drug conjugates (RDCs), dual-payload ADCs; and (iv) developing ADCs with non-cytotoxic payloads to target non-oncology diseases. Beyond cancers, we are extending our ADC focus to non-oncology drugs for treating chronic diseases that affect a large and underserved population, such as autoimmune and metabolic diseases. We believe our research has the potential to lead the next wave of innovation in ADC development.

Our ADC platform is exemplified by our pipeline, with over ten clinical and preclinical ADC assets to target some of the key mechanisms and pathways involved in cancer progression. Highlights of our ADC drug portfolio are set out below.

Clinical-stage Assets. Our clinical-stage ADC assets include SKB264, A166, and SKB315, and we currently have over ten ongoing trials being conducted in China and globally. Our ADC design strategies are exemplified by *Kthiol*, our proprietary drug-linker strategy to improve ADC stability and reduce off-target and on-target off-tumor toxicity.

- *SKB264*, one of our Core Products, is a novel TROP2 ADC targeting advanced solid tumors. Drugs that successfully target TROP2 have vast market potential as TROP2 is frequently overexpressed across a broad spectrum of cancers, especially in highly prevalent or hard-to-treat cancers such as BC, NSCLC, GC and OC. The global TROP2 ADC market is expected to increase from US\$0.7 billion in 2022 to US\$25.9 billion by 2030, representing a CAGR of 57.6%, while the TROP2 ADC market in China, following the NMPA approval of the first TROP2 ADC in June 2022, is projected to grow from RMB0.2 billion in 2023 to RMB23.6 billion by 2030 at a CAGR of 103.0%.

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Positioned to be the first domestically developed TROP2 ADC in China, SKB264 utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window. Preliminary clinical data from SKB264’s global phase 1/2 trial showed that SKB264 demonstrated encouraging ORRs across multiple types of heavily pretreated advanced solid tumors, highlighted by an ORR of 43.6%, 42.9% and 43.6% in heavily pre-treated TNBC, HR+/HER2- BC and NSCLC patients, respectively. SKB264 also demonstrated a potentially favorable safety profile. Based on non-head-to-head cross-trial comparisons, SKB264 demonstrated lower incidences of decreased neutrophil count (54% vs 78% for all grades, 26% vs 49% for \geq grade 3) and diarrhea (4% vs 59% for all grades, 0% vs 11% for \geq grade 3) compared with Trodelvy; and no incidence of treatment-related ILD compared with that reported in DS-1062-treated patients (6% for all grades and 2% for \geq grade 3). We are also exploring SKB264’s early-line potential in combination therapy. Based on preliminary results from a phase 2 trial conducted in China, SKB264 in combination with A167 demonstrating a promising ORR of 85.7% as a first-line therapy in advanced TNBC patients.

Supported by its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 outside Greater China. See “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB264” for details.

We are actively advancing a multi-strategy clinical development plan to explore SKB264’s potential as a monotherapy and combination therapies to treat various advanced solid tumors, including BC, NSCLC and other major cancers. For details, see “– Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan.”

- *A166*, another Core Product, is a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors. It is positioned to target multiple cancer indications with high prevalence and medical needs, with the potential to be one of the first domestically developed ADCs for advanced HER2+ BC in China. HER2 overexpression is widely recognized as a major driver of prevalent cancers, including BC (15-30%) and GI cancers (GC (10-30%) and CRC (3-5%)). Although three HER2 ADCs, Kadcyla Aidixi (disitamab vedotin) and Enhertu, have been approved in China, their therapeutic efficacy is limited to a minority of HER2+ solid tumor patients, thus indicating a significant unmet need for differentiated HER2 ADCs to widen the treatment options available for patients with advanced HER2+ solid tumors. The China market of HER2 ADCs is expected to increase from RMB0.6 billion in 2022 to RMB8.4 billion by 2030, representing a CAGR of 38.2%.

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Configured with a potent cytotoxic payload, clinically proven mAb and site-specific conjugation technology, A166 demonstrated promising efficacy in heavily pre-treated advanced HER2+ BC patients with an ORR of 73.9% at RP2D and in advanced HER2+ GC patients with an ORR of 31.3%, based on preliminary results from our ongoing phase 1 dose expansion study and ongoing phase 1b trial in China. A166 also showed a differentiated safety profile from that of Kadcyła, Enhertu and Aidixi, the only three NMPA and/or FDA-approved HER2 ADCs as of the Latest Practicable Date, with lower incidence of haematological, GI and lung toxicities in non-head-to-head cross-trial comparisons. Although A166 demonstrated higher incidences of ocular and peripheral nerve-related toxicities, they were reversible and generally manageable. These results suggest the potential of A166 to widen the treatment options available to advanced HER2+ solid tumor patients with different susceptibility to adverse drug reactions.

In addition to our pivotal phase 2 trial for advanced HER2+ BC, we are conducting multiple phase 1b clinical trials in China to explore the therapeutic potential of A166 for other advanced HER2+ solid tumors, including GC and CRC. For details, see “– Our Pipeline – Oncology Franchise – ADCs – A166 – Clinical Development Plan.”

- *SKB315* is a novel CLDN18.2 ADC targeting advanced solid tumors. As of the Latest Practicable Date, there were no CLDN18.2-targeting therapies approved globally. Due to its selective expression in prevalent and lethal cancers that have limited effective treatment, such as GC and PC, CLDN18.2 has been a promising target pursued by multiple biopharmaceutical and biotech companies for in-house development and licensing deals. In June 2022, we out-licensed the global development and commercialization rights for SKB315, currently in phase 1a clinical trial, to MSD. With a differentiated payload-linker design and an in-house developed humanized CLDN18.2 antibody, SKB315 demonstrated encouraging efficacy and safety across various preclinical *in vivo* tumor models with heterogeneous CLDN18.2 expression, indicating its promising therapeutic potential.

Preclinical Assets. Leveraging the accumulated expertise and know-how from our clinical-stage assets, we are accelerating the R&D of over ten preclinical ADC assets, with their respective targets expressed across a broad spectrum of solid tumors. Our preclinical assets strategically cover a range of high potential targets with a demonstrated role in cancer pathogenesis, with a focus on cancers with significant patient populations and for which there are limited or no effective treatments.

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Combination Therapies. In addition to developing ADCs as a single agent, we are exploring combination strategies to maximize the clinical value of our oncology franchise. SKB264 is being studied in two phase 2 basket studies to explore its potential as combination therapies, including SKB264 in combination with Keytruda for selected solid tumors, and SKB264 as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC. In addition, we are conducting a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC.

Comprehensive pipeline of anti-tumor drugs harnessing our multi-platform technology expertise, with strong monotherapy and combination therapy potential

We believe that cancer cannot be effectively treated with a one-size-fits-all approach. Given the complexity and heterogeneity of cancers, we believe it is crucial to equip doctors with a full arsenal of anti-tumor drugs to meet the needs with different patients with higher effectiveness. With this in mind, we have built a pipeline of six clinical-stage drug candidates and various preclinical assets, together with our ADC portfolio, to systematically treat major cancer types, such as BC, NSCLC and GI cancers, by targeting major proven mechanisms of action and targets in cancer treatment today.

Enabled by our scientific prowess and synergies across multiple platform technologies, our diversified anti-tumor drug pipeline covers both immunotherapy and targeted therapy that employs innovative mAb, bsAb and small molecule drug designs, with potential as monotherapies and combination therapies. Our powerful antibody discovery engine is equipped with both established and preminent discovery technologies to enable high throughput discovery of quality antibodies. We have also developed antibody design and engineering technologies to produce high-affinity, humanized mAbs and bsAbs with optimized pharmacological and clinical profiles. Meanwhile, our innovative small molecule platform, supported by the integration of medicinal chemistry and CADD technologies, has been instrumental in accelerating drug discovery and advancing small molecule oncology drug candidates into clinical stage. Our multi-platform technology capability has enabled us to develop differentiated assets with efficiency and quality.

Combined with our ADC platform, we are able to harness the full potential of our platform technologies to develop optimized anti-tumor drugs and extend their application to more white space indications. We focus on developing drugs for proven or well-studied targets, which can be administered as a monotherapy or in combination with our ADCs and other oncology assets. Our pipeline comprises diverse modalities including mAb, bsAb and small molecule drugs for more flexibility in exploring combination therapies.

- **A167** is expected to be our first commercialized product and the backbone of our immunotherapy franchise with an NDA submitted to the NMPA for RM-NPC in November 2021 and conditional marketing approval expected in the second half of 2023 or the first half of 2024. This approval, if granted, will be conditional partially

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upon our commitment to complete a phase 3 trial of A167 in combination with chemotherapy as a first-line treatment for RM-NPC, for which we completed patient enrollment as of the Latest Practicable Date. We are actively exploring A167’s potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise, beginning with two ongoing phase 2 trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC.

- **A140** has potential to be the first cetuximab biosimilar in China with an anticipated NDA filing in the second half of 2023, providing increased accessibility and affordability for a widely used therapeutic targeting a key pathway in many cancers, starting with rat sarcoma virus (RAS) wild-type mCRC. Driven by its high demand in China and NRDL inclusion, cetuximab (sold under the brand name Erbitux) posted annual sales of approximately €441 million in the Asia-Pacific region in 2022. A140 demonstrated pharmacokinetic (PK) equivalence to cetuximab in a phase 1 trial, with clinical equivalence being evaluated in a pivotal phase 3 trial.
- **A400** is positioned to be the first domestically developed second-generation selective RET inhibitor for NSCLC, MTC and other solid tumors with a high prevalence of RET alterations. Although two first-generation selective RET inhibitors were approved in China for RET+ solid tumors as of the Latest Practicable Date, their therapeutic benefits are limited, in part, by acquired RET drug-resistant mutations and safety issues such as hypertension and hematological toxicity, underscoring the need for novel selective RET inhibitors with improved safety and better efficacy against drug resistant mutations. The China market of selective RET inhibitors is expected to increase from RMB0.3 billion in 2022 to RMB1.8 billion in 2030, representing a CAGR of 22.9%.

We have designed A400 with a novel proprietary molecular structure to potentially address selective RET inhibitor resistance while maintaining target selectivity, efficacy and safety with reduced manufacturing cost and difficulty. Based on preliminary clinical data from its phase 1/2 trial, A400 demonstrated promising anti-tumor efficacy in patients with advanced RET+ solid tumors, highlighted by ORR of 74% and 66.7% at RP2D for 1L and 2L+ advanced RET+ NSCLC, respectively. Notably, A400 demonstrated therapeutic potential in selective RET inhibitor-resistant patients with an ORR of 33% and DCR of 83% at RP2D, as well as a potentially favorable safety profile, with no incidence of grade 3 or above lymphopenia and thrombocytopenia and substantially lower incidence of grade 3 or above cardiovascular AEs (e.g., hypertension), hematological toxicity and electrolyte abnormalities, based on non-head-to-head cross-trial comparisons with approved first-generation selective RET inhibitors. In March 2021, we granted to Ellipses an exclusive license to develop, manufacture and commercialize A400 outside Greater China and certain Asian countries.

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We are also advancing several early-stage oncology assets. SKB337 is a differentiated PD-L1/CTLA-4 bsAb in phase 1 stage, with a potentially better safety and efficacy profile than monospecific PD-L1 and CTLA4 mAbs demonstrated in preclinical studies. A289 is a phase 1-stage mAb targeting LAG3, a new-generation immune checkpoint receptor, and has demonstrated its potential to synergize with PD-(L)1 mAbs and chemotherapy to promote anti-tumor response. A296, a novel second-generation small molecule STING agonist with a differentiating molecular design, has the potential to invigorate anti-tumor immunity in “cold” tumors that are unresponsive to existing immune checkpoint inhibitors and is positioned as a combination therapy to be used with our other immunotherapy assets. Meanwhile, we are exploring combination therapies between our other immunotherapy drugs, as well as with our ADC portfolio, to expand their clinical application in broad cancer types.

Well-selected non-oncology pipeline strategically targeting diseases and conditions with immense medical needs

We have developed a differentiated non-oncology pipeline of innovative biologics and small molecule assets, including four in clinical stage. Our non-oncology pipeline covers a range of diseases and conditions with large patient populations and medical needs, including RA, AA, CKD-aP, moderate-to-severe asthma, and thromboembolic disorders and others.

A223 is potentially one of the first domestically developed small molecule JAK1/2 inhibitors in China. Inhibiting JAKs, which are key mediators of multiple pro-inflammatory cytokine signals, has proven to be effective against a number of autoimmune diseases, such as RA and AA. RA is a prevalent autoimmune disease that requires long-term treatment with approximately 6.0 million patients and an RMB17.4 billion drug market in China in 2022. Inhibiting JAKs is a clinically validated approach for treating RA, with three JAK inhibitors approved by the NMPA in China for treating RA. Among them, JAK1/2 inhibitor Olumiant has been demonstrated to better improve the symptoms of RA patients based on cross-trial comparisons. However, the approved JAK inhibitors have major safety issues, with black box warning issued by the FDA for increased risks of serious side effects including serious infection, death, malignancy, thrombosis, and major adverse cardiovascular events.

A223 is configured with a structural design that retains target selectivity with optimized pharmacological properties. This potentially translates into the encouraging safety profile demonstrated by A223 in three completed trials and two ongoing trials, where most TEAEs were mild or moderate with no incidence of black box warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated promising anti-rheumatic efficacy in moderate-to-severe RA patients, with A223 2 mg achieving substantial and statistically significant ACR20 difference of 35.1% (63.6% vs. 28.6%) and ACR50 difference of 33.7% (39.4% vs. 5.7%) at week 12 compared with placebo. Notably, based on non-head-to-head comparison, the ACR20 and ACR50 differences achieved by A223 2 mg are greater than those of Olumiant 4 mg, the approved dosage of Olumiant in China, in Chinese patients with moderate-to-severe RA (ACR20 difference vs. placebo: 30.8%; ACR50 difference vs. placebo: 20.7%). These promising clinical results indicates the potential of A223 to be an effective treatment option with improved

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efficacy and safety for RA. Besides RA, we also target AA, a common autoimmune disease that affected approximately 4.0 million people in China in 2022. Inhibiting JAK1/2 is a clinically proven approach with Olumiant being the first and only systemic treatment approved by the FDA for severe AA and one of the only two disease-specific treatments approved in China for the same indication as of the Latest Practicable Date. We expect to complete patient enrollment of our ongoing phase 2 trial for severe AA in the second half of 2023.

In addition to A223, we are also evaluating three other clinical-stage assets (A277, SKB378 and SKB336) and various preclinical assets to target indications ranging from chronic kidney disease (CKD)-associated pruritus (CKD-aP), moderate-to-severe asthma, thromboembolic disorders, to other diseases and conditions with large patient populations and medical needs. Apart from our existing assets, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

We are also extending our ADC focus beyond cancers to non-oncology drugs for treating chronic diseases that affect a large and underserved population. For example, we are exploring novel ADCs with non-cytotoxic payloads to target autoimmune and metabolic diseases.

Integrated drug development capabilities across R&D, manufacturing, quality control and commercialization

We have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization.

Our drug development capabilities are governed by a well-established management system that covers all key business functionalities, which provides a framework for our internal teams to engage in constructive dialogues and evaluation, particularly when making critical decisions for each drug development plan. We operate a three-tiered decision-making model, consisting of: (i) a pipeline committee led by our CEO that oversees the entire lifecycle of drug development programs, (ii) discovery, CMC, and clinical development committees that serve as gatekeepers for the progress and quality of our drug development programs, and provide timely feedback in each round of planning, and (iii) project leaders that are instrumental to the effective coordination among different functional groups to ensure smooth execution of our drug development plans.

Guided by this systematic approach, our integrated drug development capabilities empower us to rapidly and strategically advance a differentiated and clinically valuable pipeline of 33 assets, including 14 in clinical stage, five in pivotal trial- or NDA registration-stage, nine in phase 1- or phase 2-stage, and nine out-license agreements as of the Latest Practicable Date.

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R&D. We have a strong R&D team with rich experience and knowledge to develop our pipeline and advance our three technology platforms. Our R&D team comprises industry veterans with extensive experience of driving drug development programs at leading biopharmaceutical companies, including MNCs such as Pfizer, Wyeth, GlaxoSmithKline, Johnson & Johnson, Bristol-Myers Squibb and Novartis. Our pipeline assets are protected by a comprehensive patent portfolio, which consists of 147 issued patents, including 74 issued patents in China, 21 issued patents in the U.S. and 52 issued patents in other jurisdictions, and 255 pending patent applications as of the Latest Practicable Date.

We have a comprehensive in-house R&D engine covering drug discovery, translational medicine, process development and clinical research. Our integrated capabilities give us control and visibility over our R&D process, reduces our reliance on CROs and enable us to ensure the quality and efficiency of our drug development programs.

- *Drug Discovery.* Our drug discovery team plays a fundamental role in our development of innovative drugs to address medical needs. Our discovery team comprises medicinal chemists, computational chemists, protein scientists, biologists, immunologists and is led by experts with years of experience working at MNCs. Through bringing over ten drug candidates into clinical development, we have accumulated in-depth know-how and streamlined our drug discovery workflows for ADCs, biologics and small molecules. Our research platform support in-house capabilities covering target validation, mechanism study, candidate design and selection (including computer-aided approaches), with a goal to consistently design and engineer differentiated drug candidates with high clinical values to enrich our pipeline.
- *Translational Medicine.* Our translational medicine scientists work closely to facilitate the bridging of our drug discovery and preclinical studies with clinical needs, with an aim to bring differentiated drug candidates to market. Their interdisciplinary research encompasses a wide range of studies from drug metabolism and pharmacokinetics (DMPK), toxicology and biomarker development, to quantitative and clinical pharmacology. Our translational medicine team plays a key role in improving the success rates, time-efficiency and cost-effectiveness of our clinical trials.
- *Process Development.* Our pharmacology team is responsible for developing a quality, scalable, and robust process for our ADC, antibody and small molecule drugs. They have extensive experience in process optimization and scale-up, analytical method development, quality criteria establishment, and technology transfer. We are guided by a quality-by-design (QbD) concept to scientifically design process performance characteristics, which underlies our consistent, high-quality manufacturing of drug products.

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- *Clinical Research.* We have a robust clinical research team located across our four clinical centers in Beijing, Shanghai, Chengdu and the U.S. Our clinical scientists are highly experienced at formulating clinical development plans, selecting indications, and determining regulatory pathways. Their rich experience in regulatory communication, both in China and overseas, also plays a key role in advancing our clinical development plans towards successful commercialization.

Manufacturing and Quality Control. We believe a well-established manufacturing and quality control system serves as the cornerstone of our future commercialization and underlies our ability to enhance our R&D capabilities and advance clinical development. Our manufacturing and quality control system is capable of supporting the production of antibodies, ADCs and their key drug substances. This system helps ensure the efficiency and cost-effectiveness of our clinical trials, and facilitates a smooth transition into commercial manufacturing.

- *Manufacturing.* Our main manufacturing site in Chengdu is one of the few facilities in China with cGMP-compliant, end-to-end capabilities covering the entire development lifecycle of ADCs, from cell culture and purification, antibody production, syntheses of payloads and linkers, ADC conjugation to formulation, fill and finish. In particular, our in-house cell culture and purification facilities enable us to secure quality supplies that match our specific production requirements at significantly reduced costs, supported by two 2,000 L single-use bioreactors. We are also equipped with one 300 L ADC conjugation tank with a maximum annual production capacity of 40 batches of ADC drug substance. Our new ADC formulation center is designed with an annual output of 45 batches (or 900,000 vials) of freeze-dried ADCs or 60 batches (or 1.2 million vials) of injectable ADCs.
- *Quality Control.* We operate a comprehensive quality control system which extends across all key stages of the R&D, manufacturing and commercialization processes. This system is established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. We pay close attention to the evolving cGMP standards and regulatory developments in these target markets and update our internal procedures accordingly, striving for the highest international standards in patient safety and regulatory compliance. Furthermore, our quality expert team are actively involved in the discussion and promulgation of regulations and guidelines in China, which attests to our recognized expertise in the respective fields. For example, we took an active role in the drafting of the “Biological Products (mAb)” section of the Chinese GMP Implementation Guide (Re-issued) (中國GMP實施指南(再版)《生物製品(單克隆抗體)》部分) in 2022.

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Commercialization. We are well-positioned to develop our commercialization infrastructure and market access by leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network. Guided by Kelun Pharmaceutical’s leading industry position, strong brand image and profound resources as one of China’s largest and most established pharmaceutical companies, we are planning to develop our own commercialization team and network, with an initial focus on Class III hospitals and leading physicians across China’s extensive local markets. We will also continue to refine our commercialization strategies for each late-stage drug candidate, first prioritizing therapeutic areas with medical needs in China, such as BC, NSCLC and GI cancers, while offering synergistic treatment options enabled by our diverse pipeline to optimize patient outcome.

Cross-border business development capabilities enabling collaborations and strategic partnerships

We believe that an open and collaborative mindset is crucial to the success of our global strategy. Along each step of our drug development plans – from drug discovery to commercialization – we proactively pursue external collaborations, licensing arrangements and other strategic partnerships to create synergies with our pipeline and technology platforms.

Over the years, we have established robust, cross-border business development capabilities with local presence across multiple jurisdictions, from Chengdu, Beijing and Shanghai in China to New Jersey in the U.S. Our business development team is led by seasoned professionals with decades-long experience and insights in sourcing and executing licensing deals and collaborations. They work closely with our scientists and team leaders on each project, and are involved as early as the drug discovery stage to identify and capture partnership opportunities that maximize the clinical value of our pipeline.

Our business development competencies are exemplified by a proven track record in forging strategic partnerships worldwide, which in turn reflect the increasing recognition we have received from peers and leaders in the global biopharmaceutical industry. Notably, we have successfully negotiated nine out-license agreements to date, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical MNC. Our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world’s largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth.

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Experienced leadership backed by our Controlling Shareholder and renowned investors

We have an experienced leadership team consisting of industry veterans, regulatory experts, seasoned scientists, esteemed physicians and financial specialists. Led by our founder, Mr. Liu Gexin, and CEO, Dr. Ge Junyou, our leadership team members bring over twenty years of industry experience on average and a proven track record leading the R&D, manufacturing and commercialization of innovative drugs. Well recognized in their respective fields, they held key management roles at pharmaceutical MNCs, leading domestic biotech companies, regulatory authorities, top-grade hospitals, and renowned financial institutions.

Our leadership team is supported by a deep talent pool driving our continued innovation. As of December 31, 2022, we had 1,155 full-time employees, including 38.0% with a master’s degree or above. Through our cross-functional management system and three-tiered decision-making model, key contributors from each functional group play an active role in coordinating and overseeing our drug development plans to ensure their smooth execution, enhancing overall operational efficiency. Our team members actively participate in the formulation of industry guidelines, both in China and internationally. For example, our quality control experts are members of three working groups at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Our Controlling Shareholder Kelun Pharmaceutical has offered invaluable guidance throughout our development, and built into our genetic fabric a shared mission to bring innovative treatments to address major medical needs. Our shareholders also consist of MSD, a top-ten MNC and one of our key strategic partners, as well as blue chip healthcare investors, including renowned global institutional investors and leading domestic investors such as IDG Capital, CMG-SDIC Capital, Lilly Asia Ventures, Hillhouse, Cinda, and Sherpa. Together, our shareholders provide us with professional insights and vital connections to the biopharmaceutical industry in China and worldwide.

OUR DEVELOPMENT STRATEGIES

Advance our indication-oriented oncology pipeline

We plan to advance the clinical development of our oncology assets, with the goal to apply for regulatory approvals and initiate product launch at the earliest time practicable. Guided by our indication-oriented approach, we will continue to advance our clinical-stage and preclinical oncology assets to target cancer indications with high prevalence and medical needs, notably BC, NSCLC and GI cancers. At the same time, we will continue to explore indication expansion and combination therapies to maximize the clinical and commercial potential of our oncology pipeline.

Full coverage of major breast cancer subtypes. We have strategically targeted BC, the most common cancer worldwide with significant underserved medical needs, as our lead oncology indication with coverage by three key assets, namely, SKB264, A166 and A167 (in combination with SKB264).

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- **TNBC.** We completed patient enrollment for SKB264’s pivotal phase 3 trial in advanced TNBC patients who have failed two or more lines of treatment in April 2023 and plan to submit an NDA to the NMPA by the end of 2023. We also plan to complete SKB264’s phase 2 trial with or without A167 as a first-line treatment for advanced TNBC, and commence phase 3 trial in the first half of 2024.
- **HER2+ BC.** We completed patient enrollment for A166’s ongoing pivotal phase 2 trial in advanced HER2+ BC patients who have failed second- or later-line treatment and submitted an NDA to the NMPA in May 2023. Pending consultation with the CDE, we also plan to initiate a confirmatory phase 3 trial of A166 as a 2L+ treatment in advanced HER2+ BC patients in the second half of 2023.
- **HR+/HER2- BC.** We are advancing the dose expansion study of SKB264’s global phase 1/2 trial in advanced HR+/HER2- BC patients who have previously received at least one and no more than four lines of standard chemotherapy for metastatic disease. We completed the enrollment of this cohort in China in November 2022 and expect to advance to phase 3 in the second half of 2023.

Robust development plan for NSCLC. We are developing multiple oncology assets engineered to target different subtypes of NSCLC, the second most common cancer worldwide, with an aim to benefit patients currently without effective treatment options. In particular:

- For SKB264, we are conducting a series of clinical trials for various subtypes of NSCLC, including (i) a dose expansion study of a global phase 1/2 trial for advanced NSCLC, including advanced EGFR-wild type and EGFR-mutant NSCLC; (ii) a phase 2 trial in EGFR-mutant NSCLC patients who have failed EGFR-TKI therapy; (iii) a phase 2 trial in combination with A167 with or without chemotherapy for advanced EGFR-wild type and EGFR-mutant NSCLC, and (iv) a phase 3 trial in EGFR-mutant NSCLC patients who have failed EGFR-TKI therapy, which we expect to commence in the second half of 2023.
- In collaboration with MSD, we have commenced a phase 2 basket study of SKB264 as combination therapies (including with Keytruda, osimertinib and chemotherapy), in March 2023 in China.
- Based on the promising preliminary results of A400 in advanced RET+ NSCLC patients, we completed CDE clinical consultation and initiated a pivotal trial for 2L+ advanced RET+ NSCLC in May 2023. We also plan to commence a pivotal trial for 1L advanced RET+ NSCLC in the second half of 2023.

Expanding clinical programs for GI cancers. We are targeting GC and CRC, the two most common GI cancers worldwide. GC is the second most common cancer in China, which had approximately 43.3% of the world’s GC patients in 2022, and a leading cause of cancer death globally, while CRC is the third most common cancer and a leading cause of cancer death in China. To date, we have selected GC as a key indication for both of our Core Products,

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namely SKB264 and A166; and CRC as a key indication for A166 and A140. For GC, we are advancing the dose expansion study of SKB264’s global phase 1/2 trial in advanced GC patients who have failed first-line treatment and a phase 1b trial of A166 for advanced HER2+ GC in China. Meanwhile, SKB315 targets CLDN18.2, which is highly expressed in GC. For CRC, we are conducting a phase 1b trial of A166 in China for advanced HER2+ CRC and a pivotal phase 3 trial of A140 in combination with chemotherapy in patients with RAS wild-type mCRC in China, for which we completed patient enrollment in November 2022 and expect to file an NDA to the NMPA in the second half of 2023.

We strive to advance the clinical development of our ADCs and other drug candidates to solidify our comprehensive coverage of major tumor types and enhance our oncology portfolio.

Besides advancing our clinical-stage oncology assets, we also seek to explore the therapeutic potential of our preclinical oncology assets for a broad range of tumor types, targeting cancers with medical needs. We will continue to leverage our in-depth expertise in tumor biology and multiple drug modalities to expand our innovative oncology programs.

Advance and expand our differentiated non-oncology drug portfolio

We will continue to build and expand our differentiated non-oncology drug portfolio to target indications with significant disease burden and medical needs, leveraging our competitive ADC, biologics and small-molecule technology platforms. For A223, our small molecule JAK1/2 inhibitor, we are conducting a phase 2 trial in patients with moderate-to-severe RA and plan to initiate a pivotal phase 3 trial in the second half of 2023. We also expect to complete patient enrollment of A223’s ongoing phase 2 trial for severe AA in the second half of 2023. For A277, our peripherally-restricted KOR agonist for CKD-aP, we have completed a phase 1b clinical trial with encouraging anti-pruritic effect observed in patients on maintenance hemodialysis with moderate-to-severe CKD-aP, and we commenced a phase 2 proof-of-concept trial in September 2022. We will also continue to advance the clinical development of our two early-stage drug candidates SKB378 and SKB336.

In addition, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases. These chronic diseases are often associated with aging and exacerbated by the complex interactions of numerous lifestyle and environmental factors. We are dedicated to designing novel drug candidates and promoting R&D innovations to address these and other medical needs.

Enhance our integrated drug development capabilities

R&D. In addition to expanding our drug portfolio, we are dedicated to optimizing our R&D platforms and developing novel technologies to support the R&D of next-generation drugs. In particular, leveraging our experience and data from drug discovery, translational medicine, process development and clinical studies over years of implementing our ADC design strategies, we deploy a multi-pronged strategy to advance our ADC platform, including

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(i) further optimizing our payload/linker technologies to solidify our ADC capabilities; (ii) developing bsADCs equipped with dual-targeting antibodies to deliver enhanced clinical benefits; (iii) developing other novel ADC designs such as iADCs, RDCs, dual-payload ADCs; and (iv) developing ADCs with non-cytotoxic payloads to target non-oncology diseases. Besides developing new forms of drug conjugation, we are exploring PROTAC technology, a novel method to generate small molecules with the potential to induce degradation of a target protein. We aim to improve the therapeutic value and drug-like properties of the resulting PROTAC molecules through in-depth target biology research, CADD, enhanced preclinical safety evaluation methods, and other techniques that help optimize the discovery process.

Manufacturing and Quality Control. We will continue to expand our cGMP facilities to support the anticipated commercialization of our near-commercial assets. For our cell culture and purification unit, we plan to install one additional 2,000 L single-use bioreactor, bringing our total in-house capacity to 6,000 L. Going forward, we will continue to enhance our manufacturing capabilities, both through expanding our in-house capacity and through collaborating with industry-recognized CMOs. Meanwhile, we strive to upgrade and improve our comprehensive quality control system, benchmarking against the highest international standards adopted by pharmaceutical MNCs, to ensure patient safety and regulatory compliance.

Commercialization. Based on the expected approval timeline of each late-stage project in our pipeline, we expect to receive conditional marketing approval from the NMPA for A167 (PD-L1 mAb), our first innovative drug in NDA registration stage, in the second half of 2023 or the first half of 2024. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 in the China market in the second half of 2024 or the first half of 2025. In anticipation of these upcoming milestones, we are actively recruiting talents with a strong background in oncology, especially in BC, NSCLC, GI cancers and NPC, our lead indications for these late-stage assets. We plan to set up a fully-fledged commercialization team by the end of 2023 to oversee and coordinate the sales and marketing of A167, as well as the pre-marketing preparation for SKB264 and A166, laying the groundwork for rapid commercial-scale distribution upon these two ADCs’ anticipated NDA approval by the NMPA. Globally, we will continue to pursue a flexible strategy to capture the commercial value in major international markets, through forging synergistic license and collaboration opportunities worldwide.

Continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline

Following on the success of our existing license and collaboration agreements, we are actively exploring new partnership opportunities globally. We take a two-pronged business development approach to drive both our near- and long-term growth: for clinical-stage assets, we focus on forging partnerships with MNCs and leading domestic companies to accelerate our development timelines and maximize the commercial value of our pipeline; for early-stage assets and drug discovery, we seek co-development opportunities that enable us to explore new therapeutic areas and cutting-edge modalities, such as PROTAC and RDCs, and augment our

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technology platforms. Meanwhile, we are closely monitoring global opportunities to in-license new drug candidates and innovative technologies that could bring strategic synergies to our pipeline and technology platforms. We will consider whether to retain the Greater China commercial rights of, or fully out-license, our assets as we evaluate opportunities on a case by case basis. We are also committed to enhancing our collaborations with KOLs, top hospitals and academic institutions, in China and globally, to ensure our timely access to cutting-edge research and support our existing and future pipeline.

Optimize our integrated operation system to become a leading global biopharmaceutical company

We are continuously reviewing and optimizing our internal procedures, particularly our R&D management process, to enhance operational efficiency and support our growth as a fully fledged biopharmaceutical company. We also aim to attract and recruit outstanding scientific, marketing and managerial personnel to join our talent pool, in order to maintain our competitiveness in a rapidly evolving industry.

Meanwhile, we are actively seeking opportunities to expand our global footprint and raise international brand awareness. As our business continues to grow, we will adhere to our mission to address major medical needs in China and globally, and to bring world-class treatments, and a healthier and happier life, to all patients.

OUR PIPELINE

Our pipeline targets the world’s prevalent or hard-to-treat cancers, such as BC, NSCLC and GI cancers, as well as non-oncology diseases and conditions affecting a large and underserved population. As of the Latest Practicable Date, we had established a pipeline of 14 clinical-stage drug candidates, including five in pivotal trial- or NDA registration-stage. We have also assembled a diverse portfolio of preclinical assets, including four in IND-enabling stage, to further enrich our expanding pipeline targeting medical needs.

The clinical value of our pipeline and our drug development capabilities are recognized by the strategic partnerships we have forged worldwide to unlock the global market potential of key assets. To date, we have entered into nine out-license agreements, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth.

The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets.

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Product	Target	Molecule Type	Indication (Lines of Treatment)	Preclinical/IND-enabling	Phase Ia	Phase Ib/2	Registrational Pivotal Ph I/Ph III	NDA Filing	NCT/CTR No.	Commercial Rights/Partners		
ADIC	TROP2	Large	 TNBC (3L+) TNBC (1L) HR+HER2-BC (2L+) EGFR-mutant NSCLC (TKI failure) EGFR-wild type (1L) and EGFR-mutant (TKI failure) NSCLC EGFR-mutant NSCLC (1L) EGFR-wild type NSCLC (1L) and EGFR-mutant (TKI failure) NSCLC GC (2L+)	Combo with/without A167 Combo with Keytruda and/or chemo Combo with osimertinib Combo with A167 with/without platinum-based chemo	 (2H 2023) ⁶	 (2H 2023) ⁶	NCT05314734; NCT05449723; NCT05445908; CTR20221755; NCT04152499; CTR20201669; NCT05281145; CTR20222948; CTR202230825	Greater China / (ex-Greater China)				
				OC (platinum-resistant) Solid tumors (SCLC, UC, HNSCC and EC) NPC (PD-(L)1 relapse or refractory) CC (2/3L) UC (1L) OC (2L maintenance) CRPC (2L+)	Combo with Keytruda Combo with Keytruda Combo with Keytruda Combo with Keytruda Combo with Keytruda Combo with Keytruda	 NDA (conditional approval) submitted ⁴	CTR20212088 CTR20213396 CTR20212950 NCT05367635; CTR20220283; N/A	Global Global Global Global Global Global Global Global				
					HER2+ BC (3L+) HER2+ GC (2L+) HER2+ CRC (3L+)	Combo with Keytruda Combo with Keytruda Combo with Keytruda	 NDA (conditional approval) submitted ⁴	NCT03848286; NCT05294172; CTR20220691; NCT04835142; CTR20202451	Greater China / (Global/ex-China, HK, Macau) HARBOR (ex-Greater China)			
						RET+ NSCLC (1L) RET+ NSCLC (2L+)	Combo with Keytruda Combo with Keytruda	 (2H 2023) ⁶	Greater China and part of Asia / (ex-Greater China and part of Asia)			
							RET+ MTC and other RET+ solid tumors RET+ inhibitor-resistant solid tumors	 (2H 2023) ⁶	Global / (Co-development)			
					Non-oncology	PD-L1/ CTLA4 LAG3	Large	Solid tumors Solid tumors Solid tumors (intravenous infusion) Solid tumors (intratumoral injection)	Solid tumors	 (2H 2023) ⁶	CTR20211066 CTR20211028 NCT05387928; CTR20220985 NCT05449804; CTR20221772 CTR20202664 NCT05496426; CTR20221881 CTR20222274	Global Global Global Global Global Global Global
									STING JAK 1/2 KOR TSLP FXR/FXR α	Small	Rheumatoid arthritis Alopecia areata CKD- α P Ashma Thromboembolic disorders	Rheumatoid arthritis Alopecia areata CKD- α P Ashma Thromboembolic disorders

Abbreviations: TNBC: triple-negative breast cancer; BC: breast cancer; GC: gastric cancer; OC: ovarian cancer; SCLC: small-cell lung cancer; UC: urothelial cancer; HNSCC: head and neck squamous cell carcinoma; EC: endometrial cancer; CC: cervical cancer; CRPC: castration-resistant prostate cancer; CRC: colorectal cancer; CKD- α P: chronic kidney disease-associated pruritus
 Notes:
 1. Including immunotherapy and targeted therapies; 2. No phase II clinical trial is required for biosimilar drug candidates in China; 3. CDE consultation completed; 4. We completed a phase I study and are conducting a phase Ib study. Based on the NMPA's approval, we also commenced a pivotal phase 2 clinical trial. Upon meeting the primary endpoint in this trial, we filed NDA for conditional approval, which is under priority review. Although we completed the study per protocol, the trial is ongoing as certain patients responsive to the drug continue with treatment. Pending consultation with the CDE, we plan to commence a confirmatory phase 3 trial in 2H 2023; 5. CDE consultation ongoing; 6. A phase 1a and pivotal phase 2 clinical trial was completed. We commenced a confirmatory phase 3 trial upon consultation with the CDE; 7. Phase 1a/1b trial.

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Oncology Franchise – ADCs

SKB264 – A Novel TROP2 ADC, Our Core Product

Overview

SKB264 is a novel, internally discovered and developed TROP2 ADC targeting advanced solid tumors. Drugs that successfully target TROP2 have vast market potential as TROP2 is frequently overexpressed across a broad spectrum of cancers, especially in highly prevalent or hard-to-treat cancers such as BC, NSCLC, GC and OC. The global TROP2 ADC market is expected to increase from US\$0.7 billion in 2022 to US\$25.9 billion by 2030, representing a CAGR of 57.6%, while the TROP2 ADC market in China, following the NMPA approval of the first TROP2 ADC in June 2022, is projected to grow from RMB0.2 billion in 2023 to RMB23.6 billion by 2030 at a CAGR of 103.0%.

Positioned to be the first domestically developed TROP2 ADC in China, SKB264 utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window. Preliminary clinical data from SKB264’s global phase 1/2 trial showed that SKB264 demonstrated encouraging ORRs across multiple types of heavily pretreated advanced solid tumors, highlighted by an ORR of 43.6%, 42.9% and 43.6% in heavily pre-treated TNBC, HR+/HER2- and NSCLC patients, respectively. SKB264 also demonstrated a potentially favorable safety profile. Based on non-head-to-head cross-trial comparisons, SKB264 demonstrated lower incidences of decreased neutrophil count (54% vs 78% for all grades, 26% vs 49% for \geq grade 3) and diarrhea (4% vs 59% for all grades, 0% vs 11% for \geq grade 3) compared with Trodelvy; and no incidence of treatment-related ILD compared with that reported in DS-1062-treated patients (6% for all grades and 2% for \geq grade 3). We are also exploring SKB264’s early-line potential in combination therapy. Based on preliminary results from a phase 2 trial conducted in China, SKB264 in combination with A167 demonstrating a promising ORR of 85.7% as a first-line therapy in advanced TNBC patients.

Supported by its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 outside Greater China. See “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB264” for details.

We are actively advancing a multi-strategy clinical development plan to explore SKB264’s potential as a monotherapy and combination therapies to treat various types of advanced solid tumors:

- Breast Cancer. SKB264 targets TNBC and HR+/HER2- BC, two major subtypes of BC, the most common cancer worldwide. We commenced a pivotal phase 3 trial in advanced TNBC patients in April 2022, which enables SKB264 to become the first

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domestically developed TROP2 ADC to enter the pivotal stage, as well as a phase 2 trial of SKB264 monotherapy or in combination with A167, our PD-L1 mAb, as first-line treatment for advanced TNBC. We are also advancing the dose expansion study of SKB264’s global phase 1/2 trial in advanced HR+/HER2- BC patients.

- NSCLC. We are conducting a dose expansion study in advanced NSCLC patients (including EGFR-mutant NSCLC and EGFR-wild type NSCLC) as part of SKB264’s global phase 1/2 trial, and initiated a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy as an early-line treatment for NSCLC in China in May 2022. Moreover, we are collaborating with MSD on a phase 2 basket study of SKB264 as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC, which we commenced in March 2023 in China.
- Other Major Cancers. We are actively exploring the potential of SKB264 both as a monotherapy and as combination therapies for treating other major indications, including advanced GC and OC, for which no TROP2 ADCs were approved globally as of the Latest Practicable Date and where we may have a potential fast- or first-to-market advantage. We are collaborating with MSD on a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors, including recurrent or metastatic CC, advanced UC, recurrent OC and metastatic prostate cancer.

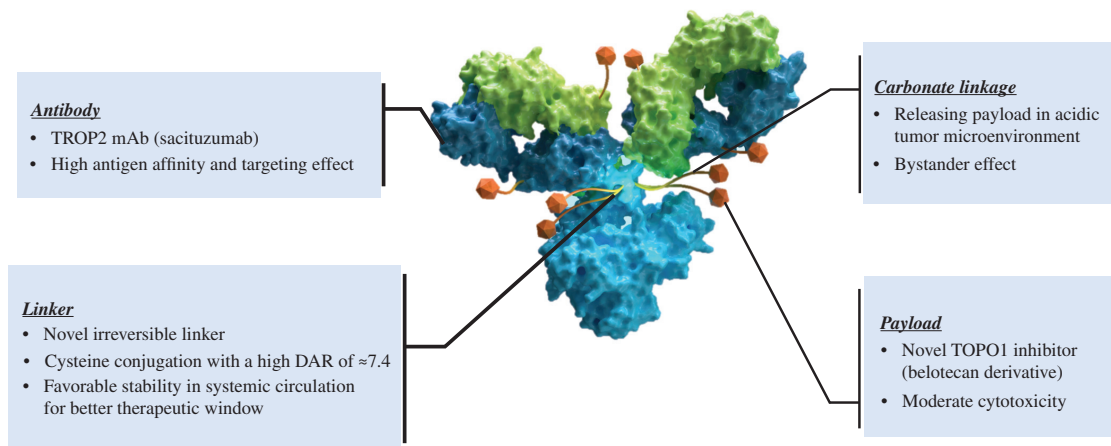
For details, see “– Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan.”

Drug Design and Mechanism of Action

TROP2 is a calcium signal transducer protein that spans the cellular membrane. TROP2 overexpression has been reported in many epithelial cancers, particularly in several prevalent or hard-to-treat cancers including BC, NSCLC, GC and OC, and is associated with tumor aggressiveness, progression, and metastasis. Given its overexpression in a wide range of tumors and low expression in normal cells, TROP2 has emerged as a promising cancer drug target.

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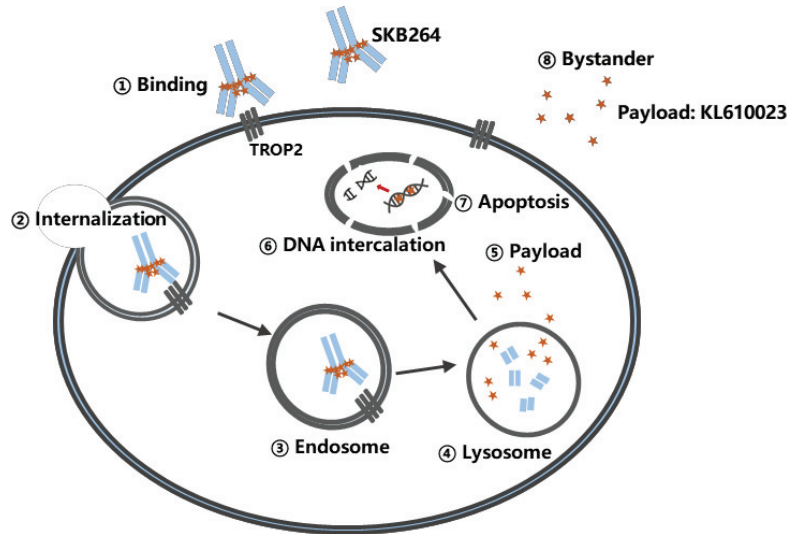
TROP2-directed therapies require complex drug design to minimize potential systemic toxicity in TROP2-expressing normal tissues. Leveraging our ADC platform and expertise, SKB264 is designed to improve upon the first FDA-approved TROP2 ADC, Trodelvy, with its core components and innovative features illustrated below.



SKB264 features a moderate payload toxicity-high DAR design, in which KL610023, a novel belotecan-derivative topoisomerase I (TOPO1) inhibitor with moderate cytotoxicity, is conjugated at a high DAR to sacituzumab, a clinically proven TROP2 mAb. Our proprietary drug-linker strategy, *Kthiol*, is used to improve ADC stability and reduce off-target and on-target off-tumor toxicity. The use of a novel carbonate linkage, which connects the antibody and payload, exploits the acidic tumor microenvironment to selectively release cytotoxic payloads in tumor tissues, thereby facilitating internalization of payloads by tumor cells and subsequent intracellular tumor killing, as well as bystander killing when payloads permeate out of ADC-targeted cells and diffuse into neighboring tumor cells. For details regarding *Kthiol*, see “– Our Technology Platforms – ADC Platform.”

Mechanistically, sacituzumab directs SKB264 selectively to TROP2-expressing tumor cells. The acid-cleavable linker then exploits the acidic pH in both the intracellular lysosome and the extracellular tumor microenvironment, releasing KL610023 both intracellularly once it is internalized by the tumor cells and extracellularly to the tumor microenvironment. The high membrane permeability of KL610023 allows KL610023 to permeate into bystander cells to which SKB264 has not bound, regardless of their TROP2 expression status. Intracellularly, KL610023 inserts itself into the DNA structure i.e., intercalation, and inhibits TOPO1, an enzyme essential to DNA replication. Inhibition of TOPO1 leads to DNA damage during the replication process, causing apoptosis. In this way, SKB264 elicits both targeted killing in TROP2-expressing tumor cells and bystander killing in TROP2-negative tumor cells, which helps overcome heterogeneity in tumors where there is uneven expression of TROP2. The diagram below illustrates the mechanism of action of SKB264:

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Market Opportunity and Competition

SKB264 has vast market potential as TROP2 is frequently overexpressed across a broad spectrum of cancers, such as BC (TNBC and HR+/HER2- BC), NSCLC, GC and OC. In May 2022, we out-licensed the development and commercialization rights for SKB264 outside Greater China to MSD, with whom we are closely collaborating on SKB264’s global clinical development.

The global TROP2 ADC market is expected to increase from US\$0.7 billion in 2022 to US\$25.9 billion by 2030, representing a CAGR of 57.6%. Following the NMPA approval of the first TROP2 ADC in June 2022, the TROP2 ADC market in China is projected to grow from RMB0.2 billion in 2023 to RMB23.6 billion by 2030 at a CAGR of 103.0%. For more details regarding the addressable market size of TROP2 ADCs, see “Industry Overview – Global and China’s TROP2 ADC Markets – Addressable Market Size of TROP2 ADCs.”

The following table summarizes the major indications targeted by SKB264.

Disease indication	Subtype	Treatment paradigm	Positioning of SKB264 ¹
BC	TNBC	First-line: single-agent or doublet chemo, chemoimmunotherapy, PARPi	3L+ (mono)
		Later-line: Trodelvy	1L (combo)
	HR+/HER2- BC	First-line: doublet endocrine therapy, combination endocrine therapy with PI3Ki/mTORi/chidamide	2L+ (mono)
		Later-line: Trodelvy (U.S.-only)	

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Disease indication	Subtype	Treatment paradigm	Positioning of SKB264 ¹
NSCLC	EGFR-mutant NSCLC	First-line: TKI	1L (combo)
		Later-line: platinum-based doublet chemo with or without bevacizumab, single-agent chemo, PD-(L)1 inhibitor	2/3L (mono) TKI failure (mono and combo)
GC	EGFR-wild type	First-line: chemoimmunotherapy with or without bevacizumab, doublet chemo with or without PD-(L)1 inhibitor, PD-(L)1 monotherapy	1L (combo)
		Later-line: PD-(L)1 inhibitor monotherapy, single-agent chemo, multi-targeting TKI	
GC	N/A	First-line HER2+: combination chemo with trastuzumab, PD-1 inhibitor (PD-L1-positive only)	2L+ (mono)
		Later-line HER2+: similar to that of HER2-GC with the addition of combination chemo with trastuzumab, HER2 ADC Aidixi (China-only)	
		First-line HER2-: doublet or triplet chemo, PD-1 inhibitor (PD-L1-positive only)	
		Later-line HER2-: single-agent chemo, other chemo regimens, PD-1 inhibitor, apatinib	
OC	Recurrent and metastatic OC	First-line: debulking surgery with platinum doublet chemo with or without bevacizumab	2L maintenance (combo)
		Later-line platinum-sensitive: platinum doublet chemo, bevacizumab, PARPi, PD-1 inhibitor, non-platinum chemo	
		Later-line platinum-resistant: non-platinum chemo, bevacizumab, PARPi, PD-1 inhibitor	

Note:

(1) In the China market.

TNBC. BC is the most common cancer worldwide. TNBC is an aggressive subtype of BC, accounting for about 15% of total BC cases. According to Frost & Sullivan, the global incidence of TNBC increased from 306.7 thousand in 2017 to 352.2 thousand in 2022 and is expected to reach 408.8 thousand in 2030, while the incidence of TNBC in China grew from 47.3 thousand in 2017 to 51.2 thousand in 2022 and is anticipated to reach 55.6 thousand in 2030. Approximately 85% of TNBC patients are diagnosed with advanced disease, with a five-year survival rate of about 12%.

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The treatment paradigm for advanced TNBC in the U.S. and China primarily involves single-agent or doublet chemotherapy, chemoimmunotherapy that combines chemotherapy with PD-1 inhibitor (for PD-L1+ patients) and PARP inhibitor (for patients with deleterious BRCA mutations) in the front-line setting, and TROP2 ADC Trodelvy in the late-line setting. Despite the greater survival benefits provided by chemoimmunotherapy and PARP inhibitor for PD-L1+ patients and patients with deleterious BRCA mutations, respectively, PD-L1 expression (20%) and BRCA1/2 mutations (10-20%) are only present in a subset of advanced TNBC patients, underscoring a significant unmet need for therapies that can potentially treat a broader patient population. TROP2 is thus an attractive drug target for monotherapy and combination therapy, as it is overexpressed in about 88% of TNBC patients.

Although the recent approval of Trodelvy (TROP2 ADC) as a third-line and beyond (3L+) treatment improves survival in heavily pre-treated patients with advanced TNBC, many patients are unresponsive or develop resistance to Trodelvy. Moreover, the FDA issued a black box warning for Trodelvy for severe neutropenia (i.e., a lower-than-normal number of neutrophils in the blood) and severe diarrhea. Consequently, there is a substantial unmet need for safe and effective treatments. As of the Latest Practicable Date, according to Frost & Sullivan, Trodelvy was the only TROP2-directed drug approved for the treatment of advanced TNBC in the U.S. and China, and there were two TROP2 ADC candidates in phase 3 clinical trials for TNBC in the U.S. and two in China. For details of the competitive landscape of TROP2 ADCs, see “Industry Overview – Global and China’s TROP2 ADC Markets – Competitive Landscape of TROP2 ADCs in the U.S. and China.”

HR+/HER2- BC. HR+/HER2- BC is the most prevalent subtype of BC, accounting for about 55% of all BC cases. According to Frost & Sullivan, the global incidence of HR+/HER2- BC grew from 1.1 million in 2017 to 1.3 million in 2022 and is expected to reach 1.5 million in 2030, while the incidence of HR+/HER2- BC in China rose from 173.4 thousand in 2017 to 187.6 thousand in 2022 and is anticipated to reach 203.8 thousand in 2030. About 5-10% of HR+/HER2- BC patients are diagnosed with advanced disease, with a five-year survival rate of about 30%.

Endocrine therapy represents the mainstay treatment for advanced HR+/HER2- BC in the U.S. and China. However, it is estimated that 40-50% of advanced HR+/HER2- BC patients are resistant to endocrine therapy. Patients refractory to endocrine therapy currently have limited effective treatment options available, leaving a significant unmet need for effective non-endocrine therapy-based treatment. Given that TROP2 is frequently overexpressed in HR+/HER2- BC, ADCs targeting TROP2-expressing tumor cells represent a promising therapeutic strategy. As of the Latest Practicable Date, according to Frost & Sullivan, Trodelvy was the only TROP2 ADC approved for treating advanced HR+/HER2- BC in the U.S., and there was no TROP2 ADC approved for the same indication in China. There was one TROP2 ADC candidate in phase 2 or beyond for HR+/HER2- BC in the U.S. and two in China. For further details, see “Industry Overview – Global and China’s TROP2 ADC Markets – Competitive Landscape of TROP2 ADCs in the U.S. and China.”

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NSCLC. Lung cancer (LC) is the second most common cancer and the leading cause of cancer death worldwide. NSCLC represents the predominant subtype of LC and accounts for over 85% of all LC cases. According to Frost & Sullivan, the global incidence of NSCLC rose from 1.7 million in 2017 to 2.0 million in 2022 and is anticipated to reach 2.5 million in 2030, while the incidence of NSCLC in China increased from 714.2 thousand in 2017 to 836.8 thousand in 2022 and is projected to reach 1.1 million in 2030. Approximately 55% of NSCLC patients are diagnosed with advanced disease.

The treatment paradigm of advanced NSCLC in the U.S. and China can be broadly classified based on the presence or absence of actionable driver mutations, i.e., genetic mutations that drive cancer development. For driver mutation-positive advanced NSCLC, targeted therapies directed against specific actionable driver mutations, typically TKIs, are usually considered in the 1L setting. For patients who have failed TKIs, platinum-based doublet chemotherapy with or without anti-angiogenic mAb bevacizumab, single-agent chemotherapy, or PD-(L)1 inhibitor monotherapy is usually considered. For driver mutation-negative advanced NSCLC, the 1L treatment options include chemoimmunotherapy with or without bevacizumab, doublet chemotherapy with or without PD-(L)1 inhibitor, and monotherapy with PD-(L)1 inhibitor (for PD-L1+ patients). 2L+ treatment options include PD-(L)1 inhibitor monotherapy, single-agent chemotherapy, and multi-targeting TKI anlotinib (for patients who have failed two chemotherapy regimens).

Despite the available treatment options, the five-year survival rates for advanced NSCLC patients in the U.S. and China are only about 8% and less than 5%, respectively. Although the recent addition of PD-(L)1 inhibitors to standard treatments has improved the survival of patients with driver mutation-negative advanced NSCLC, many patients remain unresponsive. Meanwhile, each TKI is only clinically relevant for a subset of advanced NSCLC patients with a specific driver mutation, with an ORR ranging from 30.0-93.0%. As TROP2 is overexpressed broadly in NSCLC, TROP2 ADCs represent a promising modality for treating advanced NSCLC regardless of driver mutation status. Moreover, as ADCs are able to deliver high doses of cytotoxic payload selectively to tumor cells with reduced damage to healthy cells, they can potentially offer improved efficacy and safety compared with chemotherapy in the 1L setting, when combined with PD-(L)1 inhibitors in chemoimmunotherapy regimens. As of the Latest Practicable Date, there were no TROP2 ADCs approved for treating advanced NSCLC in the U.S. and China, and there were two TROP2 ADC candidates in phase 3 clinical trials for NSCLC in the U.S. and one in China. For further details, see “Industry Overview – Global and China’s TROP2 ADC Markets – Competitive Landscape of TROP2 ADCs in the U.S. and China.”

GC. GC is the sixth most common and the third most deadly cancer worldwide. According to Frost & Sullivan, the global incidence of GC grew from 1.0 million in 2017 to 1.2 million in 2022 and is forecasted to reach 1.4 million in 2030. According to the same source, China is one of the countries with the highest incidence of GC, accounting for approximately 44% of GC incidence in the world. The incidence of GC in China increased from 429.0 thousand in 2017 to 498.6 thousand in 2022 and is expected to reach 619.6 thousand in 2030. Approximately 40-50% of GC patients are diagnosed with advanced disease.

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The standard treatments of advanced GC in the U.S. and China comprises chemotherapy, targeted therapy such as anti-HER2 drugs and anti-angiogenic drugs, and PD-1 inhibitors. Advanced GC patients have a poor overall prognosis, with a five-year survival rate of less than 10% in both the U.S. and China, as there are limited targeted drugs available and immunotherapy has only modest efficacy. Consequently, there is a significant unmet need for innovative targeted therapies. Given that TROP2 is overexpressed in approximately 56% of GC, ADCs targeting TROP2-expressing tumor cells represent a promising therapeutic strategy. As of the Latest Practicable Date, there were no TROP2 ADCs approved for treating advanced GC in the U.S. and China, and there was one TROP2 ADC candidate in phase 2 clinical trial for GC only in the U.S. For further details, see “Industry Overview – Global and China’s TROP2 ADC Markets – Competitive Landscape of TROP2 ADCs in the U.S. and China.”

OC. OC is the third most common and the fifth deadliest cancer of the female reproductive system worldwide. According to Frost & Sullivan, the global incidence of OC rose from 289.3 thousand in 2017 to 326.4 thousand in 2022 and is anticipated to reach 379.9 thousand in 2030, while the incidence of OC in China increased from 52.0 thousand in 2017 to 57.0 thousand in 2022 and is expected to reach 62.4 thousand in 2030. Approximately 70% of OC patients are diagnosed with advanced disease.

Chemotherapy represents the cornerstone treatment for advanced OC in the U.S. and China. Despite standard treatments, the prognosis of advanced OC patients remains poor, with a five-year survival rate of about 30% in the U.S. and around 30-40% in China. Given that TROP2 is overexpressed in approximately 59% of OC, TROP2 ADCs targeting TROP2-expressing tumor cells represent a promising therapeutic strategy. As of the Latest Practicable Date, there were no anti-TROP2 ADCs approved for treating advanced OC in the U.S. and China, and there were two TROP2 ADC candidates in phase 2 or beyond for OC in the U.S. and one in China. For further details, see “Industry Overview – Global and China’s TROP2 ADC Markets – Competitive Landscape of TROP2 ADCs in the U.S. and China.”

Competitive Advantages

SKB264 is a novel TROP2 ADC targeting advanced solid tumors. We believe SKB264 has the following competitive advantages:

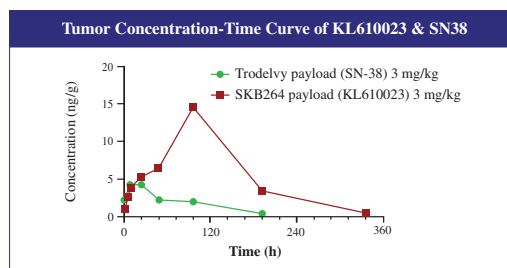
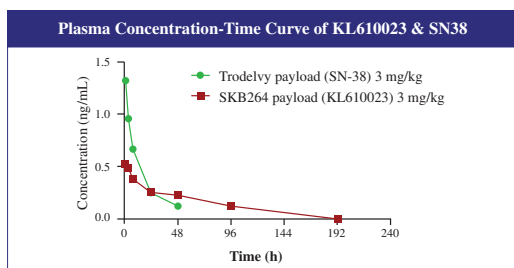
Differentiated Drug Design that Potentially Improves Therapeutic Window. SKB264 is designed with a moderately toxic payload that potentially limits toxicities to normal TROP2-expressing cells. Its high DAR enables more payload molecules to be delivered to the tumor site than systemic chemotherapy can achieve, thus potentially preventing TROP2-expressing tumor cells from repairing DNA damage.

The structure of both the payload and linker used in SKB264 contributed to increased ADC stability, thus maintaining ADC bioactivity. We used *Kthiol*, our proprietary drug-linker strategy, to improve ADC stability and reduce off-target and on-target off-tumor toxicity. Unlike the reversible addition of maleimide to cysteine in Trodelvy, the linker of SKB264 is coupled with methylsulfonyl pyrimidine as an adaptor via an irreversible covalent binding with

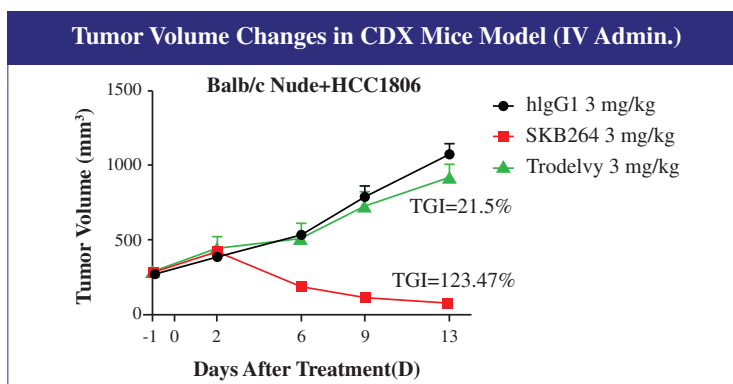
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disulfide reduced cysteine. This prevents the payload from falling off easily from the ADC in circulation. Moreover, the chemical structure of toxic payload KL610023, a belotecan-derivative TOPO1 inhibitor, also contributes to the improved stability of SKB264 in circulation. Once reaching tumor sites, the carbonate cleavage moiety in the linker allows efficient payload release to exert killing effect. This innovative design enhances the targeting ability of SKB264 while reducing its off-target and on-target off-tumor toxicity, thereby potentially leading to a broader therapeutic window.

We evaluated the anti-tumor efficacy, safety and PK properties of SKB264 alongside approved TROP2 ADC Trodelvy in a cell-line derived xenograft (CDX) model, in which immunodeficient mice were implanted with HCC1806, an established human TNBC cell line. As illustrated in the diagrams below, compared with Trodelvy at the same dose (3 mg/kg), SKB264 exhibited a comparable level of payload exposure in plasma but about 4.6 times higher payload exposure in tumor tissue, suggesting that SKB264 is more efficient in releasing cytotoxic payload in the tumor.



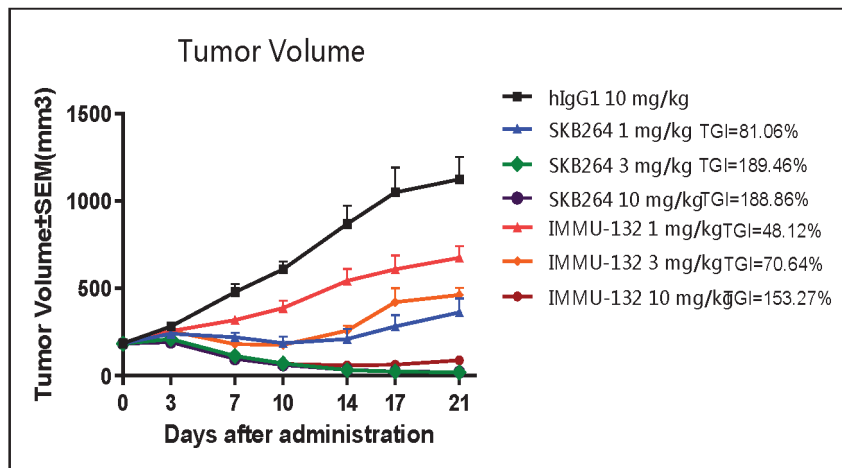
This indicates SKB264 may have a higher anti-tumor potency, evidenced by the 123.47% TGI achieved by SKB264 compared to 21.5% by Trodelvy at the same dose 13 days after treatment in a head-to-head study with Trodelvy using the HCC1806 CDX model, as shown in the diagram below. The larger intra-tumor exposure of SKB264 accounted for the greater TGI, indicating SKB264's potentially greater effectiveness in cancer treatment.



In another head-to-head study with Trodelvy using the same CDX model, treatment with SKB264 resulted in superior TGI on day 21 compared to Trodelvy at the same dose for all three doses (1, 3 and 10 mg/kg) tested in the study, as shown in the diagram below. Notably, the TGI

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achieved by 3 mg/kg of SKB264 was greater than that achieved by 10 mg/kg of Trodelvy, suggesting that SKB264 can be administered at a lower dose to minimize adverse effects while providing comparable, if not better, efficacy.



Promising Anti-tumor Activity. The differentiated drug design of SKB264 potentially contributes to its promising anti-tumor activity, supported by the preliminary clinical data from SKB264’s global phase 1/2 trial. According to the latest non-head-to-head data publicly available, SKB264 demonstrated encouraging ORRs compared with Trodelvy and DS-1062 (a phase 3-stage TROP2 ADC) as monotherapy for treating multiple types of heavily pretreated advanced solid tumors, as shown in the table below. Based on its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023.

Although no head-to-head data are available at this stage, we believe the following comparisons shed light on the differentiated features and advantages of SKB264 from an efficacy perspective.

Tumor type	SKB264	ORR	
		Trodelvy	DS-1062
TNBC ¹	43.6%	35%	32%
HR+/HER2- BC ²	42.9%	21%	27%
EGFR-mutant NSCLC ³	60.0%	N/A	35%
EGFR-wild type NSCLC ⁴	26.3%	17%	28%

Sources:

- (1) Trodelvy: ESMO2020; DS-1062: SABCS21
- (2) Trodelvy: ASCO2022; DS-1062: SABCS2022
- (3) DS-1062: ESMO 2021 (Data based on 34 NSCLC patients with actionable genomic alterations including 29 with EGFR mutations)
- (4) Trodelvy: A. Bardia, Ann Oncol 2021; DS-1062: WCLC 2021 (Data based on 50 NSCLC patients among which 84% had EGFR-wild type NSCLC)

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Potentially Favorable Safety Profile. The differentiated payload/linker design and conjugation strategy of SKB264 to reduce safety risk was reflected by the encouraging safety profile of SKB264 in clinical trials. As of the data cut-off date (August 21, 2022) and at the recommended phase 2 dose (RP2D) (5 mg/kg, Q2W) in the dose expansion cohorts from SKB264’s global phase 1/2 trial, grade 3 or above TRAEs were reported in 99 (52.7%) patients. Treatment-related serious adverse events (TRSAEs) occurred in 51 (24.2%) patients, and no TRAEs leading to death was reported.

The table below summarized the most commonly observed AEs by preferred terms for SKB264 and non-head-to-head cross-trial comparisons with Trodelvy and DS-1062. Compared with Trodelvy, SKB264 demonstrated lower incidences of decreased neutrophil count (54% vs 78% for all grades, 26% vs 49% for \geq grade 3) and diarrhea (4% vs 59% for all grades, 0% vs 11% for \geq grade 3). No incidence of treatment-related ILD was reported in SKB264-treated patients, compared with that reported in DS-1062-treated patients (6% for all grades and 2% for \geq grade 3). Although no head-to-head data are available at this stage, we believe the following comparison sheds light on the differentiated features and advantages of SKB264 from a safety perspective.

Common adverse drug reaction incidences¹ for SKB264, Trodelvy and DS-1062

Preferred Term	SKB264 5mg/kg (N=188)		Trodelvy 10mg/kg (N=258)		DS-1062 6mg/kg (N=50)	
	All grades	\geq Grade 3	All grades	\geq Grade 3	All grade	\geq Grade 3
Hematology laboratory abnormalities						
Decreased neutrophil count	54%	26%	78%	49%	N/A	N/A
Decreased hemoglobin	72%	23%	94%	9%	N/A	N/A
Decreased platelet count	32%	8%	23%	1.2%	N/A	N/A
Decreased leukocyte count	59%	17%	86%	41%	N/A	N/A
Decreased lymphocyte count	18%	4%	88%	31%	N/A	N/A
Lung-related AEs						
ILD	0%	0%	N/A	N/A	6%	2%
GI-related AEs						
Diarrhea	4%	0%	59%	11%	16%	0%
Stomatitis	44%	9%	17%	2%	60%	2%
Nausea	31%	1%	57%	3%	64%	4%
Vomiting	27%	0.5%	33%	2%	18%	0%
Constipation	5%	0%	37%	0.4%	22%	0%
Abdominal pain	2%	0%	30%	3%	N/A	N/A
Other AEs						
Rash	35%	4%	12%	0.4%	8%	0%
Alopecia	32%	0%	47%	0%	42%	0%
Decreased appetite	18%	1%	28%	2%	26%	2%

Notes:

(1) This table summarizes the common drug adverse reactions (\geq 30% all grades or \geq 2% grades 3 or 4) for SKB264, Trodelvy, or DS-1062.

Source: DS-1062: WCLC 2021; Trodelvy: Trodelvy’s drug label.

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For further details on the efficacy and safety of SKB264 in the global phase 1/2 trial, see “– Our Pipeline – Oncology Franchise – ADCs – SKB264 – Summary of Clinical Trial Data – Phase 1/2 First-in-human Clinical Trial for Selected Advanced Solid Tumors.”

Significant Early-line Potential in Combination Therapy. ADCs in combination with immune checkpoint inhibitors, such as PD-(L)1 mAbs, have the potential to improve clinical outcome. The mechanisms of action of SKB264 potentially synergize with PD-(L)1 mAbs by drawing T cells towards the tumor site, thereby facilitating immune checkpoint inhibition and exposing tumor cells to immune attacks. Our combination strategies for SKB264, including with A167 and Keytruda, potentially allow us to expand into earlier treatment lines with greater efficacy in a wide range of indications, starting from advanced TNBC and advanced NSCLC. Based on preliminary results from a phase 2 trial conducted in China, SKB264 with A167 demonstrated a promising ORR of 85.7% as a first-line treatment in advanced TNBC patients. According to the latest non-head-to-head data publicly available, Keytruda in combination with carboplatin-based doublet chemotherapy, the existing standard treatment, had an ORR of 40.8% in first-line advanced TNBC patients in a phase 3 trial.

Clinical Development Plan

We are advancing the clinical development of SKB264 with the aim to be the first domestically developed TROP2 ADC approved in China. We have adopted the following development strategies for SKB264:

Fast-to-market Monotherapy Strategy for Major Indications of Interest. Currently, patients with advanced TNBC who progressed on standard treatment have limited options, with Trodelvy being the only ADC approved in China as a 3L+ treatment as of the Latest Practicable Date. SKB264 has the potential to address this medical need based on its promising efficacy data and favorable safety profile in advanced TNBC patients. This is supported by the preliminary clinical data from SKB264’s global phase 1/2 trial, based on which SKB264 was granted Breakthrough Therapy Designation by the NMPA in July 2022. We commenced patient enrollment for a pivotal phase 3 trial in advanced TNBC patients in August 2022, enabling SKB264 to become the first domestically developed TROP2 ADC to enter the pivotal stage. We anticipate to complete patient enrollment for this pivotal trial in the second half of 2023 and submit an NDA to the NMPA by the end of 2023.

We are also advancing the dose expansion study in advanced HR+/HER2- BC patients and advanced NSCLC patients (including EGFR-mutant NSCLC and EGFR-wild type NSCLC) as part of SKB264’s global phase 1/2 trial. In China, we completed patient enrollment for the HR+/HER2- BC cohort of SKB264’s global phase 1/2 trial in selected advanced solid tumors and expect to advance to phase 3 in the second half of 2023. Notably, SKB264 was also granted Breakthrough Therapy Designation by the NMPA in January 2023 based on the encouraging efficacy and well-tolerated safety data for the treatment of EGFR-TKI failed advanced NSCLC. This designation indicates the promising potential of SKB264 for satisfying the medical needs of patients who have failed EGFR-TKI therapy, by providing a new treatment option besides chemotherapy, which remains the later-line standard treatment but has limited efficacy. We expect to commence a phase 3 trial in the second half of 2023 in EGFR-mutant NSCLC patients who have failed EGFR-TKI therapy.

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Further, we are actively exploring the potential of SKB264 for treating other major indications, including advanced GC, OC and other tumor types, for which no TROP2 ADCs were approved globally as of the Latest Practicable Date and where we may have a potential fast- or first-to-market advantage. We are enrolling more patients in the dose expansion cohorts in SKB264’s global phase 1/2 trial.

Earlier Treatment Line Expansion via Combination Therapies with Our Backbone Immunotherapy Asset. SKB264-mediated tumor cell killing may synergize with immunotherapies such as PD-(L)1 inhibitors by drawing more T cells to the tumor site and enhancing anti-tumor immunity. To explore this potential synergy, we are evaluating the combination potential of SKB264 with our lead immunotherapy candidate, A167 (PD-L1 mAb), in the front-line setting for various prevalent and hard-to-treat tumor types, starting with advanced EGFR-wild type and EGFR-mutant NSCLC (with or without chemotherapy) and advanced TNBC. We initiated a phase 2 trial to evaluate SKB264 plus A167 with or without chemotherapy as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC in May 2022 and a phase 2 trial to evaluate SKB264 with or without A167 as a first-line treatment for advanced TNBC in July 2022.

Collaborating with MSD to Advance a Multi-Strategy Clinical Development Plan. We are collaborating with MSD on SKB264’s global phase 1/2 trial, as well as two phase 2 basket studies: (i) SKB264 in combination with Keytruda for selected solid tumors, including recurrent or metastatic CC, advanced UC, recurrent OC and metastatic prostate cancer, which we commenced in December 2022 in both China and the U.S. following IND approvals from the NMPA and FDA in July 2022 and November 2022, respectively, and (ii) SKB264 as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC, for which we commenced in China in March 2023 and submitted an IND application to the FDA in January 2023. For details, see “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB264.”

The table below sets forth our clinical development plan for SKB264:

Indication (Lines of Treatment)	Trial phase	Mono-/ Combo-therapy	Trial status	(Expected)	Hospital sites ⁽¹⁾	Principal investigator(s) ⁽¹⁾	Expected trial end date	
				Trial start date				
Advanced TNBC (3L+)	Phase 3	Mono	Ongoing	April 2022	China	56	Xu Binghe, MD, Yin Yongmei, MD	2H 2025
EGFR-mutant NSCLC (TKI failure)	Phase 3	Mono	CDE consultation completed	(2H 2023)	China	N/A	Zhang Li, MD	2H 2026
TNBC (1L)	Phase 2	Combo with or without A167	Ongoing	July 2022	China	23	Yin Yongmei, MD, Ouyang Quchang, MD	1H 2025
Advanced EGFR-wild type (1L) and EGFR-mutant NSCLC (TKI failure)	Phase 2	Combo with A167 with or without platinum-based chemo	Ongoing	May 2022	China	21	Zhang Li, MD	2H 2024

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Indication (Lines of Treatment)	Trial phase	Mono-/ Combo-therapy	Trial status	(Expected) Trial start date	Location	Hospital sites ⁽¹⁾	Principal investigator(s) ⁽¹⁾	Expected trial end date
Advanced EGFR-wild type (1L), EGFR-mutant (TKI failure) and EGFR-mutant (1L) NSCLC	Phase 2	Combo with Keytruda, osimertinib and chemo	China: Ongoing	China: Mar 2023	China ⁽⁴⁾	2	Zhang Li, MD	2H 2025
EGFR-mutant NSCLC (2/3L)	Phase 2	Mono	Ongoing	Dec 2022	China	19	Zhang Li, MD	1H 2025
NPC (PD-(L)1 relapsed or refractory)								
Advanced solid tumors ⁽²⁾	Phase 1/2	Mono	Completed: dose escalation Ongoing: dose expansion	China: Jun 2020 U.S.: Nov 2019	China, U.S.	70 (China), 10 (U.S.)	Li Jin, MD, Jordi Rodon Ahnert, MD, PhD	China and U.S.: 2H 2025
Advanced solid tumors ⁽³⁾	Phase 2	Combo with Keytruda	China and U.S.: Ongoing	China and U.S.: Dec 2022	Global	11 (China), 4 (U.S.), 1 (Australia)	Wu Xiaohua, MD, Ye Dingwei, MD, Wang Jing, MD	China: 2H 2025 U.S.: 2H 2026

Notes:

- (1) Based on public information on ClinicalTrials.gov and ChinaDrugTrials.org.cn.
- (2) Including TNBC, HR+/HER2- BC, NSCLC (including EGFR-wild type NSCLC and EGFR-mutant NSCLC), GC, OC, SCLC, UC, HNSCC and EC.
- (3) Including recurrent or metastatic CC (2/3L), advanced UC (1L), recurrent and metastatic OC (2L maintenance), and advanced CRPC (2L+).
- (4) As of the Latest Practicable Date.

Summary of Clinical Trial Data

We were conducting seven clinical trials for SKB264 as of the Latest Practicable Date. In China and the U.S., we have initiated a phase 1/2 first-in-human clinical trial for selected advanced solid tumors, with dose escalation completed and dose expansion ongoing. Preliminary data from our phase 1/2 clinical trial, including our ongoing dose expansion study, have supported our further clinical trials. We are conducting a pivotal phase 3 clinical trial for advanced TNBC in China upon receiving no material objection from the NMPA. We have also consulted with the CDE regarding a phase 3 clinical trial in EGFR-mutant NSCLC patients who have failed EGFR-TKI therapy, which we plan to initiate in the second half of 2023. In addition to monotherapy trials, we have initiated four clinical trials to investigate SKB264 as part of combination therapies, including two combination trials of SKB264 with A167 in China for advanced NSCLC and advanced TNBC, respectively and a phase 2 basket study of SKB264 as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC in China. Set forth below is a summary of the key data from SKB264’s clinical trials.

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Pivotal Phase 3 Clinical Trial for Advanced TNBC

This is a randomized registrational trial of SKB264 in patients with locally advanced unresectable, recurrent or metastatic TNBC who have failed 2L+ prior standard of care. This trial plans to enroll 254 adult subjects across about 50 clinical research centers in China.

Trial Objectives. The primary endpoint is the PFS assessed by an independent review committee (IRC) based on response evaluation criteria in solid tumors guideline version 1.1 (RECIST 1.1). The secondary endpoints are the PFS assessed by trial investigators, ORR, DCR (disease control rate), duration of response (DOR), time to objective response (TTR) assessed by the IRC and trial investigators according to RECIST 1.1, overall survival (OS) and quality of life of patients evaluated using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire.

Trial Progress. As of the data cut-off date (September 30, 2022), the trial was ongoing, with first-patient-in achieved in August 2022 and 39 patients enrolled in both the experiment group and control group.

Trial Design. Patients are randomized 1:1 into the experiment group and control group, stratified by the number of previous treatment lines (2-3 vs > 3) and presence of liver metastases (yes vs no). The experiment group receives 5 mg/kg of SKB264 via intravenous (IV) injection on day 1 and day 15 of each 28-day cycle. The control group receives one of the following chemotherapy drugs via IV injection: eribulin, gemcitabine, vinorelbine, or capecitabine. Treatment cycle will continue until no more clinical benefits, intolerable toxicity, or patient requesting to discontinue study treatment.

Phase 2 Clinical Trial for Advanced NSCLC with A167 with or without Platinum-based Chemotherapy

This is an open-label, multi-center trial to assess the safety, tolerability profile and the preliminary anti-tumor activity of SKB264 in combination with A167 with or without platinum-based chemotherapy in patients with advanced or metastatic NSCLC. This trial plans to enroll no more than 110 adult subjects across about 20 clinical research centers in China.

Trial Objectives. The primary endpoints are the incidence and severity of AEs, and ORR as assessed by the investigator according to RECIST v1.1 of SKB264 in combination with A167 with or without chemotherapy in patients with advanced or metastatic NSCLC. The secondary endpoints are PFS, DOR, DCR assessed by the investigator according to RECIST v1.1, OS, PK and immunogenicity. The exploratory endpoint is to assess the correlation between anti-tumor activity and the expression level of TROP2 and PD-L1 in tumor tissue.

Trial Progress. As of the data cut-off date (November 29, 2022), this trial was ongoing, with 31 patients with first-line EGFR-wild type advanced NSCLC enrolled and treated with SKB264 5 mg/kg and A167 1200 mg administered every three weeks (Q3W).

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Trial Design. This trial comprises three treatment cohorts. Eligible patients with EGFR-wild type or EGFR-mutant NSCLC are assigned to different cohorts to receive SKB264 5 mg/kg Q3W and KL-A167 1200 mg Q3W with or without platinum-based chemotherapy (carboplatin AUC 5 mg/ml/min or cisplatin 75 mg/m², Q3W). This trial consists of two parts: the safety run-in period and the expansion period. The safety run-in is conducted in six patients to determine the safety and tolerability of SKB264 in combination with A167 with or without chemotherapy. Once the tolerability of the study treatment is confirmed by the Scientific Review Committee (SRC), subsequent enrollment in expansion period can be continued.

Phase 2 Clinical Trial for Advanced TNBC with or without A167

This is a multi-center, open-label trial to assess the safety, tolerability profile, and the preliminary anti-tumor activity of SKB264 monotherapy or in combination with A167 in patients with advanced or metastatic TNBC who have received no prior systemic therapy. This trial plans to enroll no more than 95 adult subjects across about 17 clinical research centers in China.

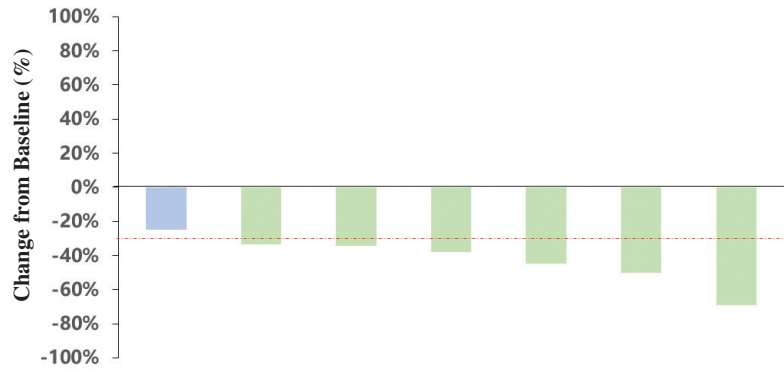
Trial Objectives. The primary endpoints are the incidence and severity of AEs, and ORR as assessed by the investigator according to RECIST v1.1 of SKB264 monotherapy or in combination with A167 as first-line treatment in patients with advanced or metastatic TNBC. The secondary endpoints are PFS, DOR, DCR assessed by the investigator according to RECIST v1.1, OS, PK and immunogenicity. The exploratory endpoint is to assess the correlation between anti-tumor activity and the expression level of TROP2 and PD-L1 in tumor tissue.

Trial Progress. As of December 6, 2022, this trial was ongoing, with first-patient-in achieved in September 2022 and eight patients with first-line advanced or metastatic TNBC treated with SKB264 5 mg/kg and A167 900 mg Q2W, with four patients on treatment for more than eight weeks.

Trial Design. This trial comprises two treatment cohorts: cohort A is SKB264 5 mg/kg Q2W in combination with A167 900 mg Q2W and cohort B is SKB264 monotherapy. This trial is divided into two parts, part 1 is to explore the safety and the preliminary efficacy of SKB264 in combination with KL-A167. In part 2, patients are randomly divided into the combination group and monotherapy group in a 1:1 ratio.

Efficacy Data. As of the data cut-off date (December 29, 2022), there were seven response-evaluable patients with first-line advanced or metastatic TNBC administered with SKB264 in combination with A167. Of seven response-evaluable patients, six patients achieved PR and one patient had SD with target lesion shrinkage of 25% at first scan. The ORR was 85.7% (including unconfirmed response) and DCR was 100%. The waterfall plot below shows the best percentage change from baseline in target lesions for each evaluable patient.

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Safety Data. As of data cut-off date (December 6, 2022), SKB264 in combination with A167 was generally safe and well-tolerated among the eight patients enrolled who received at least one dose of SKB264 in combination with A167. Eight patients (100%) had at least one TRAE related to SKB264 at any grade. Three patients (37.5%) experienced grade 3 or above TRAE. No patient experienced SKB264 or A167-related SAE. TRAEs related to SKB264 are summarized in the table below.

Preferred term	SKB264 5mg/kg +KL-A167 900mg Q2W (N=8)	
	All grades (n, %)	≥ Grade 3 (n, %)
Any TRAE	8 (100)	3 (37.5)
TRSAE	0	0
Neutropenia	5 (62.5)	1 (12.5)
Lymphopenia	5 (62.5)	0
Anemia	3 (37.5)	0
Thrombocytopenia	3 (37.5)	1 (12.5)
Rash	5 (62.5)	0
Stomatitis	5 (62.5)	0
Alopecia	4 (50)	0
Vomiting	2 (25)	0
Weakness	2 (25)	1 (12.5)

Conclusion. The combination therapy of SKB264 with A167 showed a potentially favorable safety profile and its efficacy results demonstrated promising anti-tumor activity as first-line treatment in patients with advanced or metastatic TNBC.

Phase 1/2 First-in-human Clinical Trial for Selected Advanced Solid Tumors

This is an open-label, multi-center, single-arm, first-in-human clinical trial of SKB264. This trial consists of two parts: dose escalation study in patients with advanced solid tumors and dose expansion study in patients with selected advanced tumor types. Dose escalation was conducted in 30 patients across two clinical research centers in China and eight clinical research centers in the U.S. We plan to enroll 430 patients for dose expansion across 36 clinical research centers in China and nine clinical research centers in the U.S.

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Trial Objectives. For the dose escalation study, the primary endpoints were the maximum tolerated dose (MTD) and recommended doses for expansion (RDEs) of SKB264. The secondary endpoints were the overall safety and tolerability profile, ORR, DOR, PFS, OS, the level of anti-drug antibodies (ADA), i.e., the incidence of ADA formation to SKB264, levels of TROP2 expression in tumor tissue, and PK of SKB264. For the dose expansion study, the primary endpoint is ORR. The secondary endpoints include the levels of ADA, levels of TROP2 expression in tumor tissue, PK profile, RDEs, DOR, PFS, and OS of SKB264.

Trial Progress. Dose escalation was completed in December 2021, with 30 patients enrolled and dosed at 2 mg/kg (n=4), 4 mg/kg (n=7), 5 mg/kg (n=7), 5.5 mg/kg (n=5) and 6 mg/kg (n=7). As of December 29, 2022, patient enrollment for the dose expansion cohort was ongoing, with 226 patients enrolled and dosed at 4 mg/kg or 5 mg/kg Q2W.

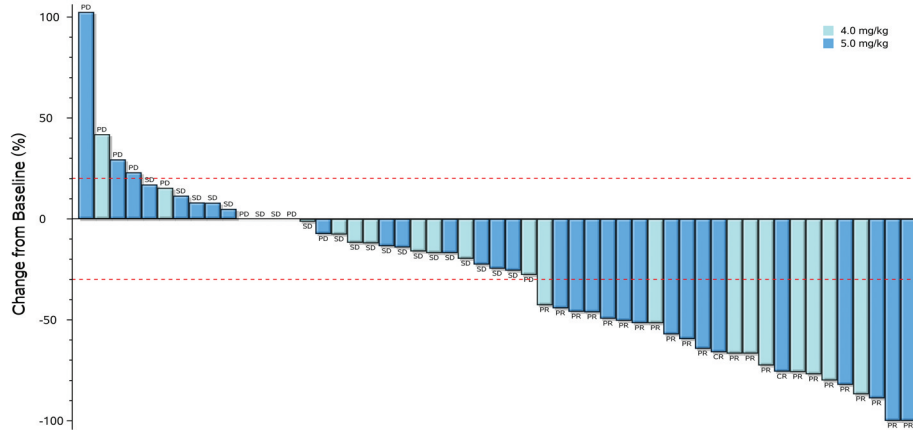
Trial Design. A Bayesian logistic regression model (BLRM) was adopted in the dose escalation study. Five dose levels were selected for evaluation in the dose escalation study of the trial: 2, 4, 5, 5.5 and 6 mg/kg. Two doses will be given on day 1 and day 15, respectively, for each 28-day cycle of SKB264 treatment. The BLRM evaluated the toxicity of all planned dose levels and some intermediate dose levels. RDEs were selected for the dose expansion cohort based on the safety, efficacy and PK data in dose escalation. Once a dose level was proved to be tolerated with potential clinical benefits in dose escalation, it would be considered as one of the RDEs.

Efficacy Data.

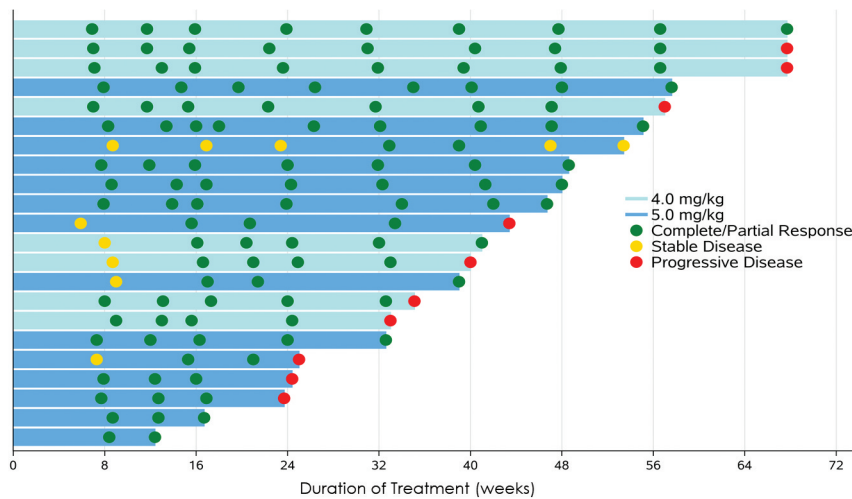
Advanced TNBC. Our advanced TNBC data was presented in the 2022 San Antonio Breast Cancer Symposium (SABCS), one of the world's largest scientific conferences dedicated to breast oncology advancements. As of the data cut-off date (October 10, 2022), 59 patients were enrolled (23 in 4 mg/kg Q2W, 36 in 5 mg/kg Q2W), 88% of patients had received ≥ 3 prior therapies for metastatic disease. The median follow-up was 12.8 months.

Of 55 patients (21 in 4 mg/kg and 34 in 5 mg/kg) evaluable for response assessment (defined as a patient with at least one post-baseline tumor assessment), the ORR was 43.6% (24/55), and DCR was 80% (44/55). The median duration of response (DoR) was 11.5 months and the 6-month DoR rate was 77.5%. The median PFS was 5.7 months. Preliminary OS data were encouraging and 12-month OS rate was 66.4%. Among the 53 patients who had tumor response and tissue available for TROP2 testing, 29 patients (55%) had high TROP2 expression (H-score >200-300). The confirmed ORR (cORR), i.e., a PR/CR maintained through a subsequent efficacy assessment at least 28 days later, was 55.2% (16/29) in the subset of patients with high TROP2 expression. The below waterfall plot shows the best percentage change from baseline in target lesions for each evaluable patient.

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The swimmer plot below shows the durable objective responses and disease stabilization of the patients who achieved confirmed partial response (PR) or complete response (CR).



HR+/HER2- BC. As of the data cut-off date (Nov 15, 2022), 39 patients were enrolled and treated with SKB264. Of 28 patients evaluable for response assessment, the ORR was 42.9% (12/28, 2 pending confirmation) and DCR was 85.7% (24/28).

NSCLC. As of the data cut-off date (February 9, 2023), 43 patients were enrolled (all in 5 mg/kg, Q2W), with a median follow-up of 11.5 months. Of 39 patients evaluable for response assessment, the ORR was 43.6% (17/39, 2 pending confirmation), DCR was 94.9% (37/39), median DoR was 9.3 months and the 6-month DoR rate was 76.9%. For EGFR wild-type subgroup (previously received median 2 lines of therapy including anti-PD-(L)1 therapy), the ORR was 26.3%, DCR was 89.5% (17/19), median PFS was 5.3 months and 9-month OS rate was 80.4%. For the subgroup with TKI-resistant EGFR-mutant NSCLC (among which 50% also failed at least one line of chemotherapy), the ORR was 60.0% (12/20), DCR was 100% (20/20), median PFS was 11.1 months and 9-month PFS rate was 66.7%.

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Safety Data. SKB264 was safe and well-tolerated in the completed dose escalation study. TRAEs were reported in 28 (93.9%) patients enrolled in the dose escalation study. 17 (56.7%) patients experienced grade 3 or above TRAEs, with the most frequent ones (incidence $\geq 5\%$) being anemia (26.7%), neutropenia (23.3%), leukopenia (16.7%), stomatitis (16.7%) and thrombocytopenia (13.3%). Patients recovered from all TRAEs of grade 3 or above after corresponding treatment. There were no TRAEs that resulted in death.

As of the data cut-off date (August 21, 2022), 211 patients had received at least one dose of SKB264 in the dose expansion study. 23 and 188 patients with different types of advanced solid tumors were treated with SKB264 at the dose level of 4 mg/kg Q2W and 5 mg/kg Q2W, respectively. Treatment-related adverse events (TRAEs) were reported in 202 (95.7%) patients. TRAEs of grade 1 or 2 occurred in 101 (47.9%) patients and were recovered with supportive care or after dose modification. Grade 3 or above TRAEs were reported in 110 (52.1%) patients. Treatment-related serious adverse events (TRSAEs) occurred in 51 (24.2%) patients. No TRAEs leading to death was reported. The safety profile of SKB264 monotherapy was tolerable and manageable. TRAEs at the dose level of 4 mg/kg Q2W and 5 mg/kg Q2W are summarized in the table below.

TRAEs at the dose of 4 mg/kg Q2W and 5 mg/kg Q2W⁽¹⁾

Preferred term	SKB264 4 mg/kg Q2W (N=23)		SKB264 5 mg/kg Q2W (N=188)	
	All grades	\geq Grade 3	All grades	\geq Grade 3
	(n, %)	(n, %)	(n, %)	(n, %)
Any TRAE	23 (100)	11 (47.8)	179 (95.2)	99 (52.7)
Anemia	17 (73.9)	4 (17.4)	136 (72.3)	44 (23.4)
Leukopenia	17 (73.9)	3 (13.0)	113 (60.1)	32 (17.0)
Neutropenia	14 (60.9)	2 (8.7)	106 (56.4)	49 (26.1)
Nausea	10 (43.5)	0	58 (30.9)	2 (1.1)
Vomiting	10 (43.5)	0	50 (26.6)	1 (0.5)
Stomatitis	6 (26.1)	1 (4.3)	82 (43.6)	16 (8.5)
Alopecia	3 (13.0)	0	60 (31.9)	0 (0.0)
Rash	6 (26.1)	0	66 (35.1)	8 (4.3)
Thrombocytopenia	6 (26.1)	3 (13.0)	65 (34.6)	15 (8.0)

Note:

- (1) Data cut-off as of August 21, 2022. All grade TRAEs occurred in $\geq 20\%$ of patients or \geq Grade 3 TRAEs occurred in > 1 subjects.

PK Data. In PK analysis in the dose escalation study, the exposure of SKB264 increased proportionally with dose within the tested dose range of 2 to 6 mg/kg. No accumulation of SKB264 was observed after multiple doses. The half-lives of SKB264 and free payload were approximately 36 hours and 49 hours, respectively, supporting a once every two weeks dosing regimen. The plasma exposure of the free payload, indicated by maximum plasma

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concentration (C_{max}) and area under the curve (AUC), were approximately 6% and 5%, respectively, as those of SKB264 in the first 4-week cycle, while the PK parameters and plasma exposure of the total antibody, which refers to conjugated, partially unconjugated and fully unconjugated antibodies, were similar to those of SKB264. These results suggested that the linker of SKB264 was stable during systemic circulation and most payload molecules were directed by the targeted antibody to the tumor tissue.

Conclusion. SKB264 monotherapy exhibited a potentially favorable safety profile in patients with advanced solid tumors and its preliminary efficacy results demonstrated encouraging anti-tumor activities across a range of tumor types.

Material Communications and Next Steps

We received IND approvals from the NMPA in April 2020 and the FDA in August 2019 for the initiation of SKB264’s global phase 1/2 trial for advanced solid tumors. We completed the phase 1 dose escalation part of the global phase 1/2 trial in December 2021. Taking into the industry practice as advised by Frost & Sullivan and as advised by PRC Legal Advisers with respect to PRC laws and regulations, the phase 1 dose escalation study was a completed clinical trial with its main purpose aligning with the overall purpose of a conventional phase 1 trial, and therefore the completion of the phase 1 dose escalation study is equivalent to the completion of a conventional phase 1 trial. We completed consultation with the CDE in April 2022 on our preliminary phase 1/2 results and the trial design of our pivotal phase 3 trial for advanced TNBC. The CDE expressed no major concerns on the preliminary results of our phase 1/2 clinical trial and no objection to the commencement of this pivotal phase 3 trial for advanced TNBC.

The NMPA granted Breakthrough Therapy Designation to SKB264 for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. We commenced our pivotal phase 3 trial for advanced TNBC in China in April 2022 and expect to complete patient enrollment in the second half of 2023.

For SKB264 combination therapies, we obtained IND approvals from the NMPA in March and April 2022 for two phase 2 clinical trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC. Further, we received IND approvals from the NMPA and FDA in July 2022 and November 2022, respectively, for a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors, which we commenced in December 2022 in China. For SKB264’s phase 2 basket study as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR wild-type and EGFR-mutant NSCLC, we commenced the trial in March 2023 in China after receiving IND approval from the NMPA in January 2023. We also submitted an IND application to the FDA for this basket study in January 2023.

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The table below sets forth the timeline of preclinical studies and clinical trials for SKB264.

<u>Milestone/Stage</u>	<u>Timeline</u>	<u>Hospital sites</u>	<u>Principal investigator(s)</u>
Preclinical development (PCC to IND-enabling stage)	March 2018 – July 2019	N/A	N/A
IND approval	U.S.: August 2019	N/A	N/A
Phase 1/2 trial for selected advanced solid tumors	China: April 2020 <i>Dose escalation</i>	70 (China), 10 (U.S.)	Li Jin, MD, Jordi Rodon Ahnert, MD, PhD
	U.S.: November 2019 – December 2021 China: June 2020 – December 2021 <i>Dose expansion</i>		
Pivotal phase 3 trial for advanced TNBC	U.S.: November 2019 – ongoing China: June 2020 – ongoing April 2022 – ongoing	56	Xu Binghe, MD, Yin Yongmei, MD
Phase 2 trial for advanced NSCLC with A167 with or without platinum-based chemotherapy	May 2022 – ongoing	21	Zhang Li, MD
Phase 2 trial for advanced TNBC with or without A167	July 2022 – ongoing	23	Yin Yongmei, MD, Ouyang Quchang, MD
Phase 2 basket study for advanced EGFR-wild type and EGFR-mutant NSCLC with Keytruda, Osimertinib and chemotherapy	China: March 2023 – ongoing U.S.: IND submitted	2 (China)	Zhang Li, MD
Phase 2 trial for EGFR-mutant NSCLC and NPC	December 2022 – ongoing	19	Zhang Li, MD
Phase 2 basket study for advanced solid tumors with Keytruda	U.S. and China: December 2022 – ongoing	11 (China), 4 (U.S.), 1 (Australia)	Wu Xiaohua, MD, Ye Dingwei, MD, Wang Jing, MD

As of the Latest Practicable Date, we had received no major concerns or objections from the NMPA or FDA to our clinical development plan for SKB264.

SKB264 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

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A166 – A Differentiated HER2 ADC, Our Core Product

Overview

A166 is a differentiated, internally discovered and developed HER2 ADC in NDA registration stage for treating advanced HER2+ solid tumors. It is positioned to target multiple cancer indications with high prevalence and medical needs, with the potential to be one of the first domestically developed ADCs for advanced HER2+ BC in China. HER2 overexpression is a well-established oncogenic driver across a wide range of cancers, including prevalent cancer types, such as BC and GI cancers (GC and CRC). Although three HER2 ADCs, Kadcyła, Aidixi and Enhertu, have been approved in China, their therapeutic efficacy is limited to a minority of HER2+ solid tumor patients, leaving a significant unmet need for differentiated HER2 ADCs to widen the treatment options available for advanced HER2+ solid tumor patients.

Configured with a potent cytotoxic payload, clinically proven mAb and site-specific conjugation technology, A166 demonstrated promising efficacy in heavily pre-treated advanced HER2+ BC patients with an ORR of 73.9% at RP2D and in advanced HER2+ GC patients with an ORR of 31.3% , based on preliminary results from our ongoing phase 1 dose expansion study and ongoing phase 1b trial in China. A166 also showed a differentiated safety profile from that of Kadcyła, Enhertu and Aidixi, the only three NMPA and/or FDA-approved HER2 ADCs as of the Latest Practicable Date, with lower incidence of haematological, GI and lung toxicities in non-head-to-head, cross-trial comparisons. Although A166 demonstrated higher incidences of ocular and peripheral nerve-related toxicities, they were reversible and generally manageable. This suggests the potential of A166 to widen the treatment options available to advanced HER2+ solid tumor patients with different susceptibility to adverse drug reactions.

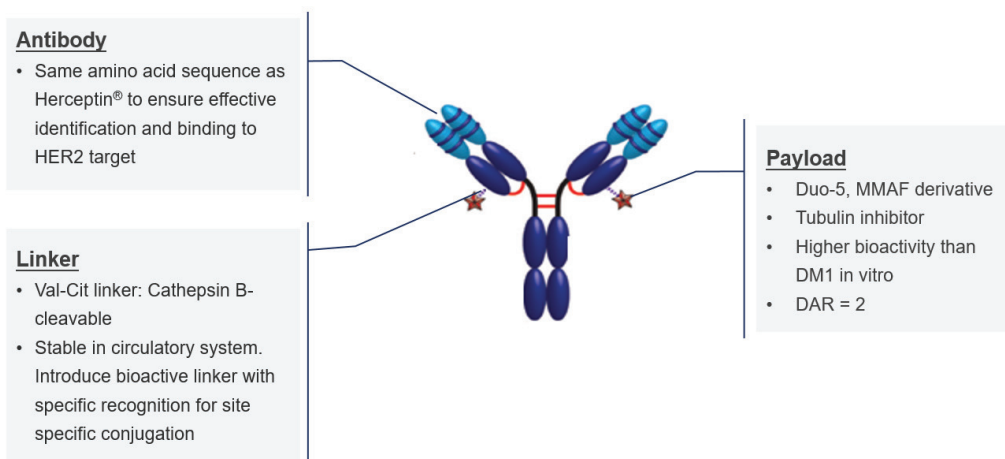
We have designed a multi-indication clinical development plan to advance A166 in China. In May 2023, we submitted an NDA to the NMPA for A166 as a 3L+ treatment for patients with advanced HER2+ BC. We completed the dose escalation study of a phase 1 trial for advanced HER2+ solid tumors with the dose expansion study anticipated to be concluded in the second half of 2024. We are conducting a pivotal phase 2 trial for advanced HER2+ BC, in which A166 has met the primary endpoints based on results from the primary analysis, which we used to submit an NDA to the NMPA in May 2023. In addition to advanced HER2+ BC, we are exploring the therapeutic potential of A166 for other advanced HER2+ solid tumors, including GC and CRC, in ongoing phase 1b clinical trials.

Drug Design and Mechanism of Action

HER2 is a cell surface receptor expressed at low levels in various tissues such as the breast, lungs, and GI tract, where it promotes cell growth and survival. In tumor cells, mutations or amplification in the HER2 gene may result in the overexpression of HER2, i.e., excessive copies of the HER2 protein, which drives uncontrollable cell growth that promotes cancer development.

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A166 is developed with the following core components and features to optimize safety and efficacy.

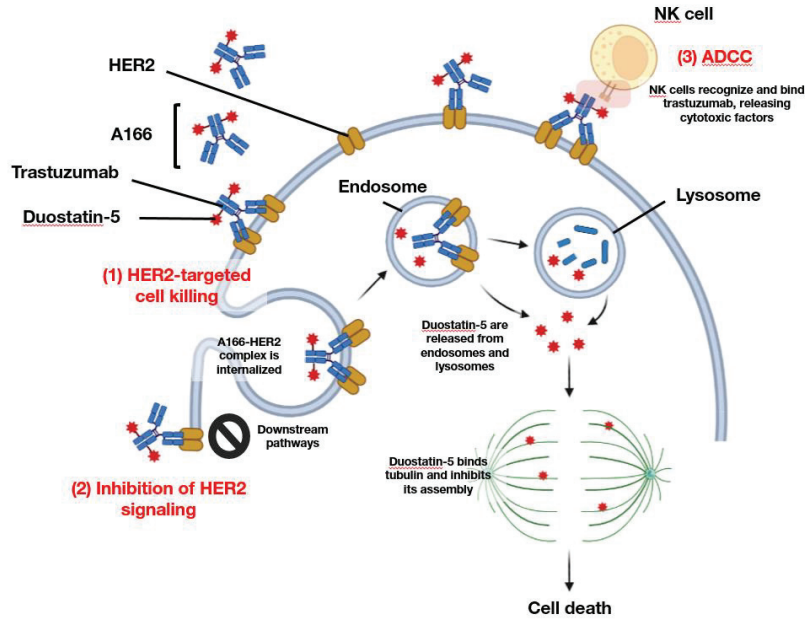


Abbreviations: Duo-5: duostatin-5; MMAF: monomethyl auristatin F; Val-Cit: valine-citrulline; DM1: emtansine

It employs a high payload toxicity-low DAR design, in which a novel, highly cytotoxic tubulin inhibitor, duostatin-5, is conjugated at a low DAR via a stable, enzyme-cleavable linker to a HER2 mAb, which has the same amino acid sequence as Herceptin (trastuzumab), a clinically proven HER2 mAb, to ensure effective identification of and binding to HER2. We use site-specific conjugation technology to generate ADCs with a homogeneous DAR.

As illustrated in the diagram below, the design of A166 potentially enables strong anti-tumor activity via HER2-targeted cell killing, inhibition of HER2 signalling and antibody-dependent cellular cytotoxicity (ADCC). Following its binding to the HER2 receptor via trastuzumab, the A166-HER2 complex is internalized and transported via the endosome-lysosome pathway, which is a system of membrane-enclosed compartments where degradative enzymes cleave the valine-citrulline linker. This releases duostatin-5, which then binds to and inhibits the assembly of tubulin, a major protein required for the maintenance of cellular architecture, thereby interfering with the cell division cycle and triggering apoptosis that kills the tumor cells. Moreover, trastuzumab, the mAb component of A166, can block HER2 from propagating oncogenic signals to downstream signalling molecules, thereby inhibiting the major signalling route that HER2+ tumor cells rely on for growth and expansion. Further, trastuzumab can trigger ADCC, an immune-mediated attack, in which trastuzumab is recognized and bound by natural killer (NK) cells, which can release cytotoxic factors that kill the A166-bound tumor cells.

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Market Opportunity and Competition

We are developing A166 in China to treat patients with advanced HER2+ solid tumors, including HER2+ BC, HER2+ GC and HER2+ CRC. The China market of HER2 ADCs is expected to increase from RMB0.6 billion in 2022 to RMB8.4 billion by 2030, representing a CAGR of 38.2%. For more details regarding the competitive landscape of HER2 ADCs in China, see “Industry Overview – China’s HER2 ADC Market – Competitive Landscape of HER2 ADCs.”

The following table summarizes the major indications targeted by A166.

Disease indication	Sub-type	Treatment paradigm	Positioning of A166 ¹
BC	HER2+ BC	First-line: combination chemo with trastuzumab and pertuzumab, doublet chemo with trastuzumab	3L+
		Later-line: combination chemotherapy with TKI or HER2 mAb, HER2 ADC (Kadcyla)	
GC	HER2+ GC	First-line: combination chemo with trastuzumab, PD-1 inhibitor (PD-L1-positive only)	2L+
		Later-line: combination chemo with trastuzumab, single-agent chemo, other chemo regimens, PD-1 inhibitor, Aidixi (China-only), apatinib	

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Disease indication	Sub-type	Treatment paradigm	Positioning of A166 ¹
CRC	HER2+ CRC	<p>First-line: PD-1 inhibitor, FOLFOX or FOLFIRI with or without cetuximab or bevacizumab, CAPEOX, chemo with or without bevacizumab</p> <p>Later-line: FOLFOX/FOLFIRI with or without cetuximab or bevacizumab, CAPEOX with or without bevacizumab</p>	3L+

Note:

(1) In the China market.

HER2+ BC. HER2+ BC is a major subtype of BC and accounts for approximately 15-30% of total BC cases. Compared to HER2– BC, HER2+ BC is associated with more aggressive, fast-growing tumors and a worse prognosis. About 20-25% of all patients with HER2+ BC have advanced disease at diagnosis, and about 20% of early-stage patients eventually develop advanced disease. According to Frost & Sullivan, the incidence of HER2+ BC in China increased from 80.1 thousand in 2017 to 86.6 thousand in 2022 and is expected to reach 94.1 thousand in 2030.

The treatment paradigm for advanced HER2+ BC patients eligible for HER2 mAb trastuzumab in China primarily involves combination chemotherapy with two HER2 mAbs, trastuzumab and pertuzumab, or doublet chemotherapy with trastuzumab in the first-line setting, combination chemotherapy with TKI pyrotinib or HER2 mAb in the 2L setting, and triple-combination therapy involving a HER2 mAb pertuzumab or TKIs, and other chemotherapy in the 3L setting. For advanced HER2+ BC patients not eligible for trastuzumab, the treatment paradigm in China primarily involves combination chemotherapy with TKI pyrotinib in the first-line setting, HER2 ADC Kadcyla monotherapy and combination chemotherapy with TKI lapatinib in the 2L setting, and combination chemotherapy with TKI neratinib, TKI pyrotinib monotherapy and other TKI/HER2 mAb-chemotherapy combinations in the 3L setting. HER2 ADC Enhertu monotherapy is also approved for patients with unresectable or metastatic HER2+ BC who have received one or more prior anti-HER2-based regimens. Despite the advances in anti-HER2 therapies, a significant number of patients remain unresponsive or experience treatment resistance and/or significant side effects. Kadcyla and Enhertu, for example, carry notable safety concerns, including black box warning issued by the FDA for hepatic, cardiac and embryo-fetal toxicities for Kadcyla, and interstitial lung disease and embryo-fetal toxicity for Enhertu. These limitations highlight a significant unmet need for safer treatments that can prolong the survival for relapsed or refractory patients. As of the Latest Practicable Date, according to Frost & Sullivan, Kadcyla and Enhertu were the only HER2 ADCs approved for advanced HER2+ BC in China, and there were nine HER2 ADCs in China in phase 2 or beyond for treating advanced HER2+ BC. For further details, see “Industry Overview – China’s HER2 ADC Market – Competitive Landscape of HER2 ADCs.”

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HER2+ GC. GC is the sixth most common and the third most deadly cancer worldwide, with China being one of the countries with the highest GC incidence. HER2 overexpression is reported in approximately 10-30% of GC patients, and it represents an important actionable oncogenic alteration in GC. According to Frost & Sullivan, the incidence of HER2+ GC in China increased from 102.5 thousand in 2017 to 119.2 thousand in 2022 and is expected to reach 148.1 thousand in 2030. Approximately 50% of HER2+ GC patients are diagnosed with advanced disease.

In China, the early-line treatments for HER2+ GC primarily involve combination chemotherapy with HER2 mAb trastuzumab and single-agent chemotherapy (in the 2L setting), with HER2 ADC Aidixi, an anti-angiogenic TKI, PD-1 inhibitors and single-agent chemotherapy available as 3L+ treatments. The use of trastuzumab in combination with chemotherapy in early-line HER2+ GC patients generally improves patient outcome compared with conventional chemotherapy. However, a significant portion of patients do not respond to trastuzumab and the majority of patients who initially benefit from trastuzumab develop drug resistance. These patients have limited effective 2L+ treatment options, with Aidixi being the only HER2-directed drug available in the 3L+ setting. This underscores a significant unmet need for novel HER2-directed drugs to overcome trastuzumab resistance and widen the treatment options for 2L+ HER2+ GC patients. As of the Latest Practicable Date, according to Frost & Sullivan, HER2 ADC Aidixi was the only HER2 ADC approved in China for advanced HER2+ GC, and there were ten HER2 ADCs in phase 1 or beyond for HER2+ GC in China. For further details, see “Industry Overview – China’s HER2 ADC Market – Competitive Landscape of HER2 ADCs.”

HER2+ CRC. CRC is the third most common cancer and one of the leading causes of cancer mortality in China. HER2 is reported to be overexpressed in approximately 3-5% of CRC. According to Frost & Sullivan, the incidence of HER2+ CRC in China increased from 16.5 thousand in 2017 to 19.3 thousand in 2022 and is expected to reach 24.1 thousand in 2030. Approximately 36% of HER2+ CRC patients are diagnosed with advanced disease.

In China, the early-line treatments for HER2+ CRC primarily involve chemotherapy with or without EGFR mAb cetuximab or anti-angiogenic mAb bevacizumab. As of the Latest Practicable Date, there were no HER2-directed drugs approved by the NMPA for advanced HER2+ CRC. The response rates of advanced HER2+ CRC patients to current non-HER2-directed standard treatments are only between 10.0% to 35.3%, leaving many patients with limited clinical benefit and highlighting the significant unmet need for novel HER2-directed drugs to improve the survival of advanced HER2+ CRC patients. As of the Latest Practicable Date, there were two HER2 ADCs in phase 1 or beyond for HER2+ CRC in China. For further details, see “Industry Overview – China’s HER2 ADC Market – Competitive Landscape of HER2 ADCs.”

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Competitive Advantages

Site-specific Low-DAR Conjugation for Highly Potent Payload. A166 is armed with a highly cytotoxic payload that can exert potent tumor cell killing at a low DAR. Coupled with a uniformly low DAR, achieved via our site-specific conjugation technology, this design potentially ensures the safety of A166 by enhancing ADC stability and reducing premature payload release in blood circulation, while maintaining robust anti-tumor potency.

Promising Anti-tumor Effect. Based on preliminary results from our ongoing phase 1 dose expansion study, A166 demonstrated promising efficacy, highlighted by an ORR of 73.9% at RP2D (4.8 mg/kg Q3W). Notably, we specifically enrolled patients whose treatment histories were in line with the current treatment paradigm for advanced HER2+ BC in China to better reflect the intended use population. In addition to its promising preliminary efficacy against advanced HER2+ BC, A166 also showed encouraging efficacy against advanced HER2+ GC with an ORR of 31.3% based on preliminary results from our ongoing phase 1b trial. Although no head-to-head data are available at this stage, we believe the following comparisons with Kadcyla, Enhertu and Aidixi shed light on the differentiated features and advantages of A166 from an efficacy perspective, based on the latest non-head-to-head data publicly available.

Tumor type	ORR			
	A166 (4.8 mg/kg Q3W)	Kadcyla	Enhertu	Aidixi
Advanced HER2+ BC ¹	73.9%	43.6%	60.9%	34.4%
Advanced HER2+ GC ²	31.3%	N/A	40.5%	24.4%

Sources:

- (1) *Kadcyla: Dieras V, et al. Lancet Oncol 2017; Enhertu: Modi S, et al. New Engl J Med 2020; Aidixi: SABCS19-PD4-06 published in February 2020*
- (2) *Enhertu: Enhertu’s drug label; Aidixi: Aidixi’s drug label*

The promising efficacy demonstrated by A166 indicates its potential as an effective treatment option for advanced HER2+ solid tumor patients in China.

Potentially Differentiated Safety Profile. Supported by its drug design for balanced efficacy and safety, A166 demonstrated high stability in systemic circulation in heavily pre-treated advanced HER2+ BC patients based on preliminary results from its overall phase 1 trial, where it showed a differentiated safety profile from Kadcyla, Enhertu and Aidixi, with lower incidence of haematological, GI and lung toxicities in non-head-to-head cross-trial comparisons. Although A166 demonstrated higher incidences of ocular and peripheral nerve-related toxicities, they were reversible and generally manageable. Although no head-to-head data are available at this stage, we believe the following comparison sheds light on the differentiated features and advantages of A166 from a safety perspective. With a differentiated safety profile, A166 has the potential to widen the treatment options available for advanced HER2+ BC patients with different susceptibility to adverse drug reactions.

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Preferred term		Kadcyla	Enhertu	Aidixi	A166
		(3.6 mg/kg, Q3W, N=490)	(5.4 mg/kg, Q3W, N=234)	(2.5 mg, Q2W, N=350)	(4.8 and 6.0 mg/kg, Q3W, N=77)
		Adverse drug reaction incidence ⁽¹⁾ (%)			
Anemia	Total	14.3	31	22.6	23.4
	≥ Grade 3	4.1	7	2.6	3.9
Decreased platelet count	Total	83	37	16.0	3.9
	≥ Grade 3	17	3.4	1.1	0
Decreased neutrophil count	Total	39	62	50.6	9.1
	≥ Grade 3	3	16	16.9	1.3
Decreased white blood cell count	Total	N/A	70	55.4	20.8
	≥ Grade 3	N/A	7	10.9	4.2
Nausea	Total	39.8	79	31.1	9.1
	≥ Grade 3	0.8	7	0.3	0
Vomiting	Total	19.2	47	18.3	5.2
	≥ Grade 3	0.8	3.8	0.6	0
Diarrhea	Total	24.1	29	11.4	9.1
	≥ Grade 3	1.6	1.7	0.3	0
Elevated aspartate aminotransferase	Total	98	41	49.7	18.2
	≥ Grade 3	<8	0.9	16	0
Elevated alanine aminotransferase	Total	82	38	42.9	18.2
	≥ Grade 3	<6	0.4	1.7	0
Peripheral neuropathy	Total	21.2	N/A	5.1	54.5
	≥ Grade 3	2.2	N/A	1.1	6.5
Corneal disease	Total	3.9	N/A	N/A	94.8
	≥ Grade 3	0	N/A	N/A	36.4
Dry eye	Total	3.9	11.1	N/A	40.3
	≥ Grade 3	0	0.4	N/A	15.6
Blurred vision	Total	4.5	N/A	N/A	85.7
	≥ Grade 3	0	N/A	N/A	24.7
ILD	Total	N/A	9.0	N/A	2.6
	≥ Grade 3	N/A	2.6	N/A	0

Note:

(1) This table summarizes the common drug adverse reactions and laboratory abnormalities (≥10% all grades or ≥2% grades 3 or 4) for A166, Kadcyla, Enhertu, or Aidixi.

Sources:

(1) Kadcyla: Kadcyla’s drug label; Enhertu: Enhertu’s drug label; Aidixi: Aidixi’s drug label

For further details about the efficacy and safety of A166 in the ongoing clinical trials, see “– Our Pipeline – Oncology Franchise – ADCs – A166 – Summary of Clinical Trial Data.”

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Clinical Development Plan

We are executing a multi-indication clinical development plan for A166 in China to explore the potential of A166 for treating various advanced HER2+ solid tumors. Based on the approval from the NMPA, we are conducting a pivotal phase 2 trial to evaluate the potential of A166 as a 3L+ treatment for advanced HER2+ BC. Upon meeting the primary endpoint in our pivotal phase 2 trial, we have filed an NDA for conditional approval in May 2023, which is under priority review. Although we have completed the study per protocol, the trial is still ongoing as certain patients responsive to the drug continue with treatment. Pending consultation with the CDE, we plan to commence a confirmatory phase 3 trial to explore A166 as a 2L+ treatment for advanced HER2+ BC in the second half of 2023. We are also conducting two phase 1b trials to evaluate A166 for patients with advanced HER2+ GC and advanced HER2+ CRC, respectively, which we expect to conclude in the first half of 2024.

The table below sets forth our clinical development plan for A166:

Indication (Lines of Treatment)	Trial phase	Trial status	(Expected) Trial start date	Hospital sites ⁽¹⁾	Principal investigator(s) ⁽¹⁾	Expected trial end date
Advanced HER2+ BC (2L+)	Phase 3	CDE clinical consultation	(2H 2023)	N/A	N/A	2H 2025
Advanced HER2+ BC (3L+)	Phase 2	Ongoing	August 2021	39	Hu Xichun, MD	2H 2023
Advanced HER2+ GC (2L+)	Phase 1b	Ongoing	December 2021	20	Liu Tianshu, MD	2H 2023
Advanced HER2+ CRC (3L+)	Phase 1b	Ongoing	December 2021	21	Xu Ruihua, MD	2H 2023
Advanced HER2+ solid tumors	Phase 1	Completed: dose escalation Ongoing: dose expansion	August 2018	3	Hu Xichun, MD	1H 2024

Note:

(1) Based on public information on ClinicalTrials.gov and ChinaDrugTrials.org.cn

Summary of Clinical Trial Data

Set forth below is a summary of the key data from A166’s completed and ongoing clinical trials.

Pivotal Phase 2 Clinical Trial for Advanced HER2+ BC

This is an open-label, multi-center, single-arm pivotal trial to evaluate the efficacy of A166 in Chinese patients with locally advanced unresectable, relapsed, or metastatic HER2+ BC who have failed 2L+ treatments. This trial is conducted in 123 adult subjects across 39 clinical research centers in China.

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Trial Objectives. The primary endpoint is the IRC-assessed ORR based on RECIST 1.1. The secondary endpoints are the ORR assessed by trial investigators, PFS, OS, survival rates, safety, immunogenicity, and PK of A166.

Trial Progress. A166 has met the primary endpoints based on results from the primary analysis, after all enrolled patients had undergone a follow-up period of at least six months. As of the Latest Practicable Date, this trial was ongoing with some patients still responsive to A166 and continuing to receive treatment.

Trial Design. Subjects receive 4.8 mg/kg of A166 injection once every 21 (± 3) days until disease progression, intolerable toxicity, death, withdrawal of informed consent, or other treatment termination criteria are met.

Phase 1b Clinical Trial for Advanced HER2+ GC or Esophagogastric Junction Adenocarcinoma

This is an open-label, multi-center, single-arm trial to evaluate the safety, tolerability and efficacy, and to determine the RP2D of A166 in 2L+ patients with locally advanced unresectable or metastatic HER2+ GC or esophagogastric junction adenocarcinoma. This trial is conducted in 16 adult subjects in 11 clinical research centers across China.

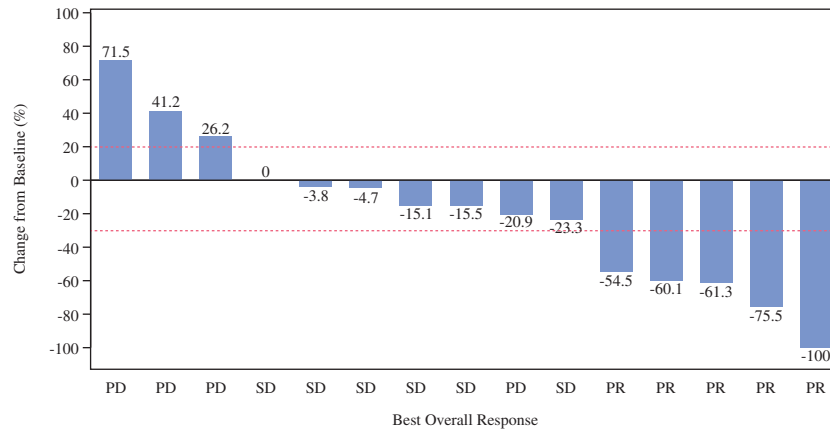
Trial Objectives. The primary endpoints include A166’s safety, tolerability and ORR. The secondary endpoints include other efficacy parameters including DOR, DCR and PFS, the PK characteristics of A166 and duostatin-5, and the immunogenicity of A166.

Trial Progress. As of the Latest Practicable Date, this trial was ongoing with patient enrollment completed in December 2022. As of February 9, 2023, 16 patients were enrolled and dosed at 4.8 mg/kg of A166 injection Q3W, with a median follow-up of 6.7 months. As of the same date, five (31.3%) patients were still receiving treatment.

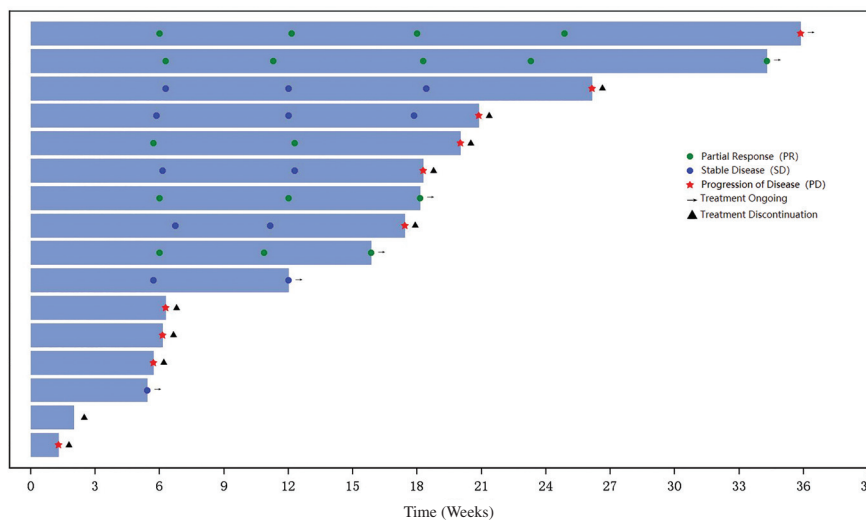
Trial Design. Subjects receive 4.8 mg/kg of A166 injection Q3W until disease progression, intolerable toxicity, or withdrawal of informed consent.

Efficacy Data. As of the data cut-off date (February 9, 2023), of 16 patients evaluable for response assessment, the ORR was 31.3% (5/16), and DCR was 68.8% (11/16). The median PFS was 4.6 months. The below waterfall plot shows the best percentage change from baseline in target lesions for each evaluable patient.

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The swimmer plot below shows the responses of 16 evaluable patients to A166 treatment over time.



Safety Data. As of the data cut-off date (February 9, 2023), 93.8% of patients experienced TRAEs, which were mainly ocular-related and were reversible. Most frequent TRAEs in the 16 evaluable patients were blurred vision (68.8%), corneal epitheliopathy (68.8%), dry eye (50.0%), neutropenia (25.0%), lymphopenia (25.0%), anemia (25.0%) and weight loss (25.0%). Grade 3 or higher TRAEs were reported in 37.5% of patients.

Conclusion. A166 was generally safe and well-tolerated in 2L+ advanced HER2+ GC patients with promising anti-tumor efficacy, based on preliminary results.

Phase 1 Clinical Trial for Advanced HER2+ Solid Tumors (KL166-I-01-CTP;CTR20181301)

This is a single-arm, dose-escalation and dose expansion trial to evaluate the safety, tolerability, PK, and anti-tumor activity of A166 in Chinese patients with locally advanced unresectable or metastatic HER2+ solid tumors who progressed on or did not respond to available standard therapies. The dose escalation study was conducted in 25 patients and the dose expansion study plans to enroll 71 patients across three clinical research centers in China.

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Trial Objectives. The primary endpoint of the dose escalation study was the maximum tolerated dose (MTD) and recommended stage 2 dose (RS2D) of A166. The secondary endpoints were the dose-limiting toxicity, safety, preliminary efficacy, PK and immunogenicity of A166. The primary endpoint of the dose expansion study was the ORR. The secondary endpoints are the safety, DCR, PFS, OS, and PK of A166.

Trial Progress. The dose escalation study was completed in April 2020. As of the Latest Practicable Date, patient enrollment of the dose expansion study was ongoing, with first-patient-in achieved in May 2020.

Trial Design. This trial consists of two parts, i.e., dose escalation and dose expansion. In the dose escalation study, patients were randomly assigned into eight cohorts to receive escalating doses of A166 from 0.1 to 6.0 mg/kg, administered once every three weeks. In the dose expansion study, patients are randomly assigned to receive A166 at the RS2D (either 4.8 or 6.0 mg/kg).

Efficacy Data. In the completed phase 1 dose escalation study, A166 demonstrated promising anti-tumor activity across dose levels from 0.1 to 6 mg/kg with five patients achieving PR and a DCR of 45.5% in the 25 patients who underwent at least one efficacy assessment.

In the ongoing phase 1 dose expansion study, as of the data cut-off date (July 13, 2022), 58 patients enrolled in the 4.8 and 6.0 mg/kg A166 cohorts were evaluable for response assessment, all of whom had prior HER2-targeted therapy with a median four lines of prior treatments, including 100% (58/58) received trastuzumab, 94.8% (55/58) received anti-HER2 TKIs, 32.8% (19/58) received pertuzumab, and 20.7% (12/58) received anti-HER2 ADCs in which eight received T-DM1, three received ARX-788 (HER2 ADC) and one received TAA-013 (HER2 ADC).

As illustrated in the table below, A166 achieved an overall ORR of 70.7% (41/58), with an ORR of 73.9% (17/23) in the 4.8 mg/kg cohort and 68.6% (24/35) in the 6.0 mg/kg cohort. The median PFS was 12.3 months in the 4.8 mg/kg cohort and 9.4 months in the 6.0 mg/kg cohort. The median DOR was 11.0 months in the 4.8 mg/kg cohort and 8.3 months in the 6.0 mg/kg cohort.

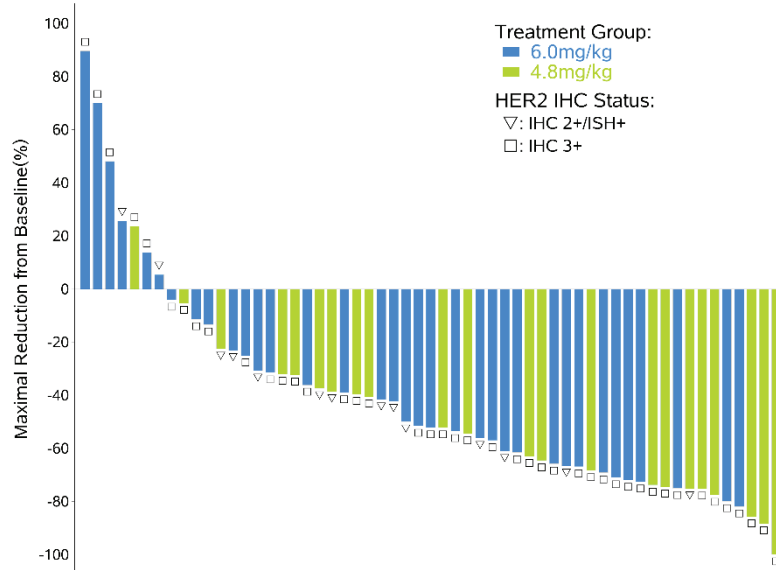
Best Responses for HER2+ BC Patients in 4.8 and 6.0 mg/kg Cohorts

	4.8 mg/kg (N=23)	6.0 mg/kg (N=35)	Total (N=58)
ORR	73.9%	68.6%	70.7%
DCR	82.6%	80.0%	81.0%
mPFS (months)	12.3	9.4	10.2
mDOR (months)	11.0	8.3	8.5

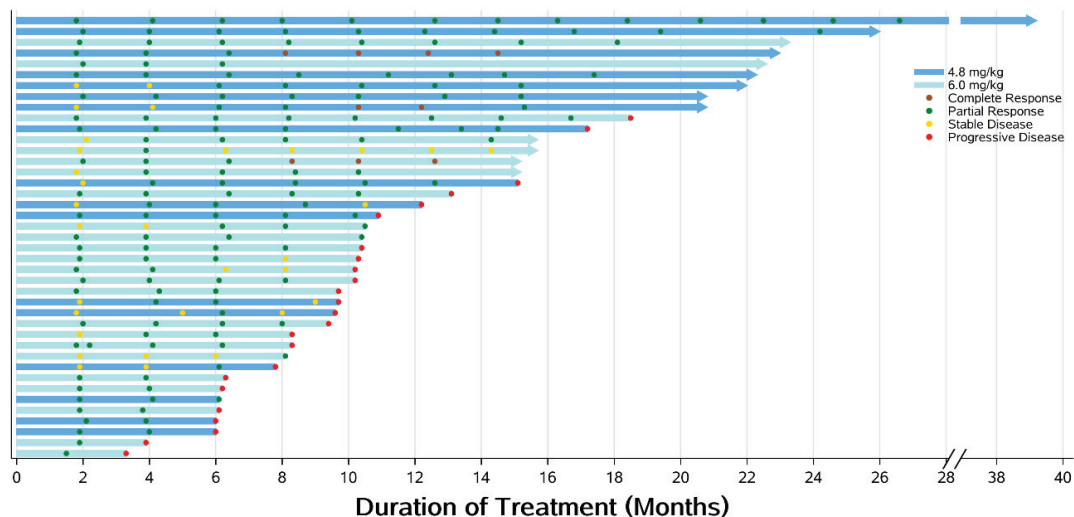
Abbreviations: CR, complete response; PR, partial response; ORR, objective response rate (CR + PR); DCR, disease control rate (CR + PR + SD); mPFS: median PFS; mDOR: median duration of response

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The below waterfall plot shows the best percent change from baseline in target lesions for each evaluable patient who had PR or CR.



The swimmer plot below shows the durable objective responses and disease stabilization of the patients who achieved PR or CR. Overall, these results demonstrated the encouraging anti-tumor activity of A166 in heavily pretreated HER2+ BC patients, highlighted by an ORR of 73.9% at RP2D (4.8 mg/kg) and median PFS of more than 12 months.



Safety Data. In the completed dose escalation study, A166 was generally safe and well-tolerated with no incidence of dose-limiting toxicities observed in all dose cohorts. In the dose expansion study, as of the data cut-off date (February 28, 2022), 77 patients were evaluable for safety assessment. TRAEs were primarily ocular and peripheral nerve-related and reversible. Grade 3 or above TRAEs were reported in 61.0% (47/77) of patients. The following table illustrates the TRAEs that occurred in 10% or more patients.

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Most common TRAEs (any grade and grade \geq 3)

TRAEs No. of Patients (%)	4.8 mg/kg (N=29)		6.0 mg/kg (N=48)		Total (N=77)	
	Any grade	Grade \geq 3	Any grade	Grade \geq 3	Any grade	Grade \geq 3
Overall	29 (100)	16 (55.2)	48 (100)	31 (64.6)	77 (100)	47 (61.0)
Corneal epitheliopathy	28 (96.6)	11 (37.9)	45 (93.8)	17 (35.4)	73 (94.8)	28 (36.4)
Blurred vision	24 (82.8)	7 (24.1)	42 (87.5)	12 (25.0)	66 (85.7)	19 (24.7)
Peripheral neuropathy	17 (58.6)	1 (3.4)	25 (52.1)	4 (8.3)	42 (54.5)	5 (6.5)
Dry eyes	10 (34.5)	3 (10.3)	21 (43.8)	9 (18.8)	31 (40.3)	12 (15.6)
Muscular weakness	11 (37.9)	1 (3.4)	11 (22.9)	2 (4.2)	22 (28.6)	3 (3.9)
Alopecia	3 (10.3)	0	16 (33.3)	0	19 (24.7)	0
Anemia	4 (13.8)	0	14 (29.2)	3 (6.3)	18 (23.4)	3 (3.9)
Creatine phosphokinase increased	8 (27.6)	0	10 (20.8)	0	18 (23.4)	0
Myoglobin blood increased	6 (20.7)	0	9 (18.8)	0	15 (19.5)	0
ALT increased	6 (20.7)	0	8 (16.7)	0	14 (18.2)	0
AST increased	6 (20.7)	0	8 (16.7)	0	14 (18.2)	0
Hypomagnesemia	8 (27.6)	0	5 (10.4)	0	13 (16.9)	0
Leukopenia	1 (3.4)	0	10 (20.8)	2 (4.2)	11 (14.3)	2 (2.6)
Hyponatremia	4 (13.8)	0	5 (10.4)	1 (2.1)	9 (11.7)	1 (1.3)
Proteinuria	3 (10.3)	0	6 (12.5)	0	9 (11.7)	0
Blood bilirubin increased	4 (13.8)	0	4 (8.3)	0	8 (10.4)	0

Note:

- (1) Most common TRAEs include TRAEs of any grade with an incidence \geq 10% and all grade 3 or above TRAEs.

All ocular-related AEs were reversible and occurred approximately after two cycles of A166 treatment, and the majority were grade 1 or grade 2, which were easy to diagnose clinically and assess severity through protocol-assigned eye examinations. Throughout the trial, we followed an optimized eye care management protocol. Patients prophylactically received artificial tears, ocular lubricants and eyedrops, according to ophthalmologist’s discretion, depending on the occurrence or grading of epitheliopathy. Treatment delay and dose reduction were used for grade 3 or 4 ocular-related AEs. In addition, unplanned visits were encouraged in the protocol in case ocular symptoms appeared or deteriorated. Using this strategy, A166-related corneal epitheliopathy was generally manageable and reversible in our patients.

PK Data. A166 demonstrated high stability in blood circulation with the exposure and maximum plasma concentration of the serum free payload duostatin-5 amounting to only 0.1% and 0.2%, respectively, as that of the total A166 ADC in the first week of administration.

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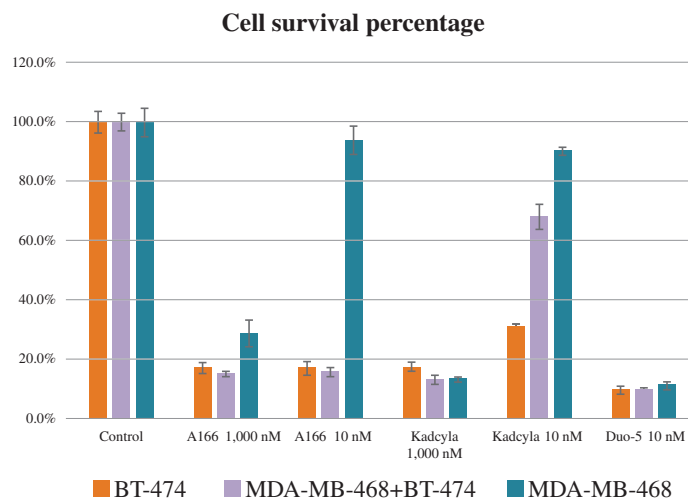
Conclusion. A166 demonstrated promising anti-tumor efficacy in previously treated advanced HER2+ solid tumors, highlighted by its rapid and durable anti-tumor activity in heavily pre-treated advanced HER2+ BC patients. It also exhibited a differentiated safety profile with high stability in blood circulation.

Summary of Preclinical Data

We performed a series of *in vitro* and *in vivo* preclinical studies to characterize the potency, toxicology, and pharmacological properties of A166.

In non-head-to-head comparison with DM-1, i.e., payload of Kadcyla, duostatin-5 demonstrated a higher *in vitro* cytotoxicity, indicated by its lower half maximal inhibitory concentration (IC₅₀) value (3.4 nM for duostatin-5 vs 14.94 nM for DM-1).

In a head-to-head cell viability and proliferation study, A166 demonstrated a stronger HER2-directed anti-tumor effect compared with Kadcyla. As shown in the diagram below, treatment with A166 (10 nM) led to an over 80% reduction in the viability of BT-474, a HER2+ BC cell line, which was near two-fold greater than that achieved by Kadcyla. Notably, A166 (10 nM) treatment also resulted in a similarly significant viability reduction in HER2– BC cell line MDA-MB-468 cocultured with BT-474, whereas Kadcyla (10 nM) treatment only led to a modest viability reduction in the cocultured cells. This suggested that A166 may have a greater bystander killing capability than Kadcyla. Importantly, A166 did not affect the viability of MDA-MB-468 when cultured alone, suggesting that the bystander killing of A166 is only effective in HER2– cells that neighbor HER2+ cells, indicating low potential for systemic toxicity.



Furthermore, *in vivo* PK-PD analysis demonstrated high stability of A166 in systemic circulation with free payload detected only in the target tissue but not in the systemic circulation in a dose-dependent manner. This result potentially contributed to the favorable toxicology profiles of A166 in rat and cynomolgus monkey studies, in which A166’s toxicities were observed in fewer organs (eyeball, lung, spleen, thymus gland and bone marrow) in non-head-to-head comparison with those of Kadcyla (liver, spleen, thymus gland, skin, tongue, sciatic nerve, spinal cord, lung and kidney) and Enhertu (intestine, lung, skin, testicle, bone marrow and kidney).

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Material Communications and Next Steps

We received IND approval from the NMPA in April 2018 for initiating A166’s phase 1 clinical trial for advanced HER2+ solid tumors in China. We completed the phase 1a dose escalation part of the phase 1 clinical trial in April 2020. Taking into the industry practice as advised by Frost & Sullivan and as advised by PRC Legal Advisers with respect to PRC laws and regulations, the phase 1a dose escalation study was a completed clinical trial with its main purpose aligning with the overall purpose of a conventional phase 1 trial, and therefore the completion of the phase 1a dose escalation study is equivalent to the completion of a conventional phase 1 trial. We consulted with the CDE in March 2021 and received their approval in June 2021 for commencing the pivotal phase 2 trial for advanced HER2+ BC in China. We initiated pre-NDA consultation with the NMPA in December 2022 regarding the NDA submission of A166 as a 3L+ treatment for patients with advanced HER2+ BC and received feedback from the CDE’s clinical division in February 2023 agreeing for us to submit an NDA under priority review, based on results from the primary analysis of the ongoing pivotal phase 2 trial which showed that A166 has met the primary endpoints. We submitted an NDA to the NMPA in May 2023. Pending consultation with the CDE, we plan to commence a confirmatory phase 3 clinical trial to explore A166 as a 2L+ treatment for advanced HER2+ BC in the second half of 2023.

The table below sets forth the timeline of preclinical studies and clinical trials for A166.

<u>Milestone/Stage</u>	<u>Timeline</u>	<u>Hospital sites</u>	<u>Principal investigator(s)</u>
Preclinical development (PCC to IND-enabling stage)	July 2015 – August 2017	N/A	N/A
IND approval	China: April 2018	N/A	N/A
Phase 1 trial for advanced HER2+ solid tumors (including BC, NSCLC, GC, CRC and others): dose escalation study	August 2018 – April 2020	3	Hu Xichun, MD
Phase 1 trial for advanced HER2+ solid tumors: dose expansion study	May 2020 – ongoing	3	Hu Xichun, MD
Pivotal phase 2 trial for advanced HER2+ BC	August 2021 – ongoing	39	Hu Xichun, MD
Confirmatory phase 3 trial for advanced HER2+ BC	Expected to be commenced in the second half of 2023	N/A	N/A
Phase 1b trial for advanced HER2+ GC	December 2021 – ongoing	20	Liu Tianshu, MD
Phase 1b trial for advanced HER2+ CRC	December 2021 – ongoing	21	Xu Ruihua, MD

As of the Latest Practicable Date, we had received no major concerns or objections from the NMPA to our clinical development plans for A166.

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A166 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB315 – A CLDN18.2 ADC

Overview

SKB315 is a novel CLDN18.2 ADC designed for treating advanced solid tumors. CLDN18.2 is highly expressed in prevalent and lethal cancers with limited effective treatments such as GC and PC, while its normal expression is restricted to gastric mucosa. This selective expression makes CLDN18.2 a promising drug target, highlighted recently by the positive clinical results of zolbetuximab, a CLDN18.2 mAb in phase 3 stage as of the Latest Practicable Date. Compared with mAbs, targeting CLDN18.2 via ADC is potentially a more efficacious therapeutic strategy as ADCs exert anti-tumor effects primarily via cytotoxic payloads and bystander effect, which may overcome low or heterogeneous CLDN18.2 expression in tumors that traditionally limits the efficacy of mAbs. With a differentiated payload-linker design and an in-house developed humanized CLDN18.2 antibody, SKB315 demonstrated encouraging efficacy and safety across various preclinical *in vivo* tumor models with heterogeneous CLDN18.2 expression, indicating its promising therapeutic potential.

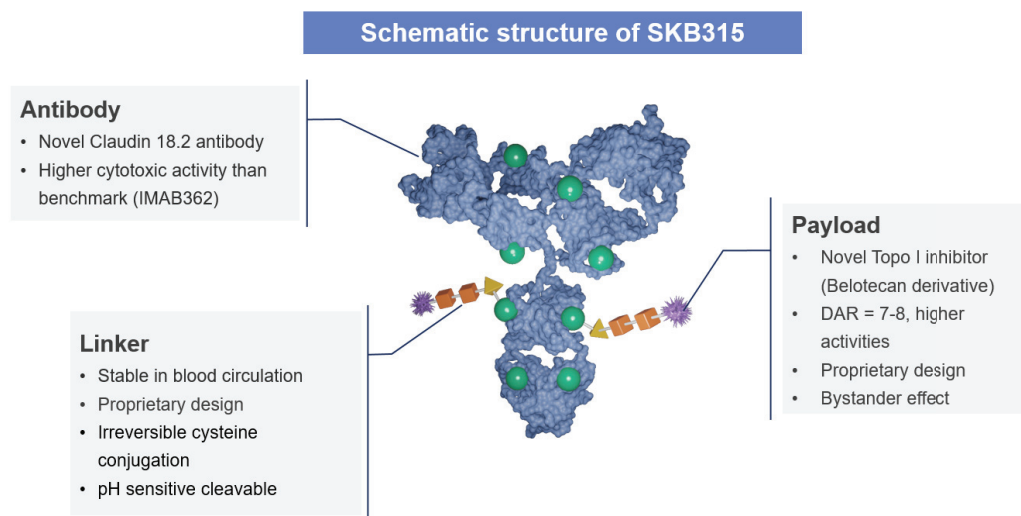
In June 2022, we entered into a license and collaboration agreement with MSD, under which we granted MSD exclusive global development and commercialization rights for SKB315. Pursuant to this agreement, we are carrying out certain activities in support of SKB315’s clinical development, including an ongoing phase 1a clinical trial of SKB315 in patients with advanced solid tumors in China, which we initiated in February 2022 and expect to complete in the second half of 2024. See “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB315” for details.

Drug Design and Mechanism of Action

CLDN18.2 belongs to a family of proteins that maintain cell junctions controlling the interchange of molecules between cells. In normal tissues, CLDN18.2 is selectively expressed in the gastric mucosa, i.e., the innermost layer of the stomach wall, making it largely inaccessible to targeting antibodies. However, the disrupted cell junctions during cancer development expose CLDN18.2 on the tumor cell surface, allowing it to be targeted by antibodies. This tumor specificity makes CLDN18.2 an attractive anti-tumor target in various cancers, such as GC and PC, where CLDN18.2 is highly expressed.

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SKB315 is a novel CLDN18.2 ADC that aims to deliver cytotoxic drugs selectively to CLDN18.2-expressing tumor cells, with an optimized design to maximize efficacy and safety. The core components and innovative features of SKB315 are illustrated below.



SKB315 is configured with a proprietary, in-house developed humanized CLDN18.2 mAb and a differentiated payload-linker design. Mechanistically, SKB315 is guided by the CLDN18.2 mAb to the CLDN18.2-expressing tumor cells, where it exerts targeted cell killing, bystander killing and immune-mediated killing via mechanisms.

Market Opportunity and Competition

CLDN18.2 overexpression has been identified in various cancers, such as GC and PC, indicating the potential of CLDN18.2 ADCs for treating a wide range of cancers. For more details regarding the addressable market size of CLDN18.2 ADCs, see “Industry Overview – Global CLDN18.2 ADC Market – Addressable Market Size of CLDN18.2 ADCs.”

Competitive Advantages

Differentiated Payload-linker Design. SKB315 is configured with a differentiated payload-linker design in which a novel, moderately cytotoxic topoisomerase I (TOPO1) inhibitor is conjugated at a high DAR to the targeting antibody. Our differentiated payload-linker design is potentially less harmful to gastric tissues where CLDN18.2 is expressed. SKB315 exhibited a good safety profile in mouse and cynomolgus monkey models where it showed a broad therapeutic window with limited and reversible organ toxicities, indicating a potentially promising safety profile in humans.

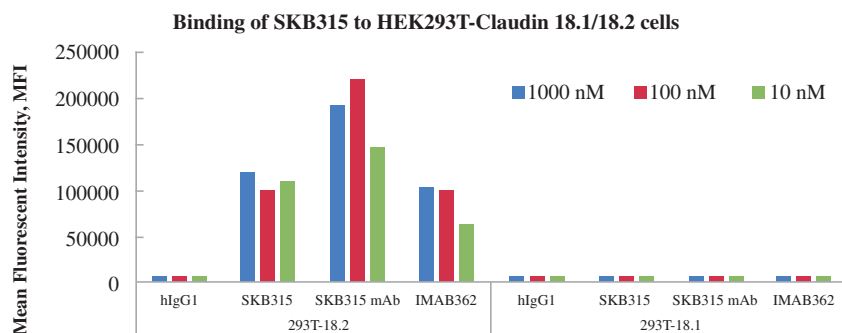
Therapeutic Potential against Tumors with High to Low CLDN18.2 Expression. Equipped with a differentiated payload-linker design and an in-house developed CLDN18.2 antibody, SKB315 demonstrated comparable CLDN18.2 specificity, comparable or greater CLDN18.2 affinity and greater proliferation inhibitory effect across multiple cancer cell lines compared with zolbetuximab in head-to-head *in vitro* studies. These features potentially contributed to SKB315’s strong anti-tumor activities in various preclinical *in vivo* tumor models with high to low CLDN18.2 expression, indicating the therapeutic potential of SKB315 for treating tumors across a wide range of CLDN18.2 expression.

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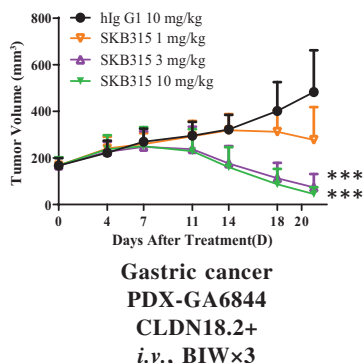
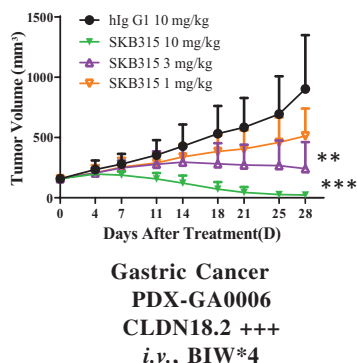
Summary of Preclinical Data

We have evaluated SKB315 in a series of preclinical studies, including (i) mechanism of action studies, (ii) PD studies *in vitro* and *in vivo* for anti-tumor activity evaluation, (iii) *in vitro* and *in vivo* PK studies of SKB315, its payload and antibody to elucidate their patterns of absorption, distribution, metabolism and excretion, and (iv) *in vitro* and *in vivo* studies to evaluate the safety of SKB315 and its payload molecule, including single-dose toxicity, repeated-dose toxicity and other toxicological assays. Notably, in a series of head-to-head preclinical studies compared with zolbetuximab (under the drug code of IMAB362) as shown in the diagrams below, SKB315 demonstrated comparable CLDN18.2 binding specificity and comparable or greater CLDN18.2 binding affinity.

Binding Affinity and Specificity of SKB315 for Injection to Human Claudin 18.1/18.2 at the Cellular Level



SKB315 has demonstrated promising *in vivo* efficacy, highlighted by its anti-tumor activities in CLDN18.2+ GC PDX model and CLDN18.2-low GC PDX model, as shown in the diagrams below.



Moreover, in a cynomolgus monkey model, which is a non-human primate model that closely resembles human, treatment with SKB315 at the highest non-severely toxic dose, which refers to the highest dose level that does not result in lethal, life-threatening or irreversible toxicities, did not result in GI or haematological toxicities, with reversible thymic lymphocyte reduction being the only detectable toxicity.

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Preclinical ADC Assets

Building on our sophisticated ADC platform and accumulated expertise from the development of clinical-stage ADCs, we are advancing over ten preclinical ADC assets that are well positioned to deliver enhanced anti-tumor efficacy and superior safety results. Furthermore, they strategically cover high potential targets with a demonstrated role in cancer pathogenesis, with a focus on cancers with significant patient populations and for which there are limited or no effective treatments.

A410 is one of our preclinical-stage ADC candidates. As of the Latest Practicable Date, there were no ADCs approved by the NMPA targeting the same tumor associated antigen (TAA) as A410. Utilizing a differentiated payload-linker strategy, A410 is equipped with a moderately toxic payload that potentially reduces toxicities, with improved therapeutic window and safety profile demonstrated in preclinical studies compared to the latest non-head-to-head data publicly available for an FDA-approved ADC targeting the same TAA. We received IND approval from the NMPA for A410 in February 2023.

In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau. For details, see “– Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets.”

OUR PRECLINICAL ADC ASSETS MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies)

A167 – A PD-L1 mAb

Overview

A167 is a humanized mAb that targets PD-L1, an important immune checkpoint protein. Targeting PD-L1 and its receptor PD-1 has become the cornerstone of cancer immunotherapy, with PD-(L)1 mAbs now widely recognised as a front-line cancer immunotherapy agent. To further elicit the anti-tumor activity of PD-(L)1 mAbs, the market has witnessed encouraging clinical development advancement of PD-(L)1 mAbs-based combination strategies in recent years, with an aim to achieve synergistic efficacies, boost response rates, overcome heterogeneity across patients, and relieve treatment resistance.

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Against this backdrop, we have developed A167 as the backbone of our immunotherapy franchise, not only as a monotherapy but, more importantly, to be used in combination with our ADCs and other oncology assets. Building on its robust efficacy and safety results in multiple monotherapy trials for advanced solid tumors such as RM-NPC, A167 in combination with SKB264 demonstrated encouraging preliminary efficacy in an ongoing phase 2 trial conducted in China, highlighted by an ORR of 85.7% in first-line advanced TNBC patients. A167’s promising clinical results underscore its therapeutic potential as monotherapy and combination therapies.

We filed an NDA with the NMPA in November 2021 and expect to receive conditional approval in the second half of 2023 or the first half of 2024 to market A167 as a 3L+ treatment for RM-NPC. This approval, if granted, will be conditional partly upon our commitment to complete a phase 3 trial of A167 in combination with chemotherapy as a first-line treatment for RM-NPC, for which we had completed patient enrollment as of the Latest Practicable Date. Moreover, we are actively exploring A167’s potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise, beginning with two ongoing phase 2 trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC.

In August 2018, we granted to Harbour BioMed an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A167 outside Greater China. For details, see “License and Collaboration Arrangements – Collaboration and Licensing Agreement with Harbour Biomed for A167.” See also “Connected Transactions – Non-exempt Continuing Connected Transaction – Licensing Agreement” for details on our patent and technology in-license agreement with Kelun Research Institute, a wholly-owned subsidiary of Kelun Pharmaceutical, in relation to A167.

Mechanism of Action

Programmed cell death ligand-1 (PD-L1) is a transmembrane protein that functions as a brake of T-cell activation via its binding to two proteins, i.e., programmed cell death-1 (PD-1) expressed mainly on activated T cells and the cluster of differentiation 80 (B7-1) protein expressed on antigen-presenting cells. The interaction of PD-L1 with PD-1 or B7-1 produces an inhibitory signal that suppresses T cell proliferation and function, which is a major immune checkpoint that helps keep immune responses in check. However, this checkpoint is often exploited by tumor cells to evade immune detection and elimination. In particular, PD-L1 is overexpressed by various cancers and certain immune cells in the tumor microenvironment (TME), contributing to an immunosuppressive TME that is favorable for tumor growth.

By modulating the interaction between immune cells and tumor cells, immune checkpoint inhibitors, such as PD-(L)1 mAbs, have become an important class of anti-cancer treatment. As a PD-L1 mAb, A167 selectively binds to PD-L1 and inhibits the association of PD-L1 with PD-1 and B7-1, thereby reawakening the suppressed anti-tumor immune response. A167 is a human IgG1 mAb with a silenced constant fragment (Fc) region to deliberately remove ADCC and complement-dependent cytotoxicity (CDC), i.e., two immune-mediated cell killing functions, to minimize toxicity towards healthy tissues.

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Market Opportunity and Competition

RM-NPC. NPC is a type of head and neck cancer that starts in the nasopharynx, i.e., the upper part of the throat behind the nose and near the base of the skull. According to Frost & Sullivan, the incidence of NPC in China increased from 59.5 thousand in 2017 to 64.0 thousand in 2022 and is expected to reach 69.1 thousand in 2030. Patients with RM-NPC account for approximately 35% of total NPC cases.

In China, the early-line treatments for RM-NPC primarily involve repeat radiotherapy (for recurrent NPC), chemotherapy and PD-1 inhibitors. The current standard of care only offers modest therapeutic benefits, with the effective rates of PD-1 mAb monotherapy ranging from approximately 20% to 30%. Given that PD-L1 is expressed in about 89% to 95% of NPC tumors, PD-L1 blockade by PD-L1 mAb is a promising therapeutic strategy to expand the currently limited treatment options for RM-NPC. As of the Latest Practicable Date, there were no PD-L1 mAbs approved by the NMPA for treating RM-NPC in China. Our NDA-filed A167 was the only PD-L1 mAb in phase 1 or beyond for treating RM-NPC in China as of the same date. For details regarding the competitive landscape of PD-(L)1 mAbs for RM-NPC in China, see “Industry Overview – China’s PD-(L)1 mAb Market – China’s PD-(L)1 MAb Market – Competitive Landscape of PD-(L)1 MAb for RM-NPC.”

Competitive Advantages

Significant early-line Potential in Combination Strategies. Combination strategies of PD-(L)1 mAbs with other cancer therapies have potential to improve clinical outcome compared with their monotherapy counterparts. As the backbone of our immunotherapy franchise, A167 enables us to formulate combination strategies with our other oncology assets such as SKB264. The targeted tumor killing by ADCs and antibodies, in particular, is expected to generate a stimulatory signal that draws T cells towards the tumor site, thus facilitating A167 to inhibit the PD-(L)1 checkpoint and expose tumor cells to immune attacks. Our combination strategies for SKB264 and A167 allow us to explore patients in earlier treatment lines with potentially greater efficacy, beginning with TNBC and NSCLC. Based on preliminary results from a phase 2 trial conducted in China, A167 in combination with SKB264 demonstrated a promising ORR of 85.7% as a first-line therapy in advanced TNBC patients, indicating the therapeutic potential of A167 as the backbone of our combination strategies. For more details of A167’s combination strategies, see “– Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A167 – Next Steps.”

Promising Anti-tumor Efficacy and Safety Profile. A167 demonstrated a promising clinical efficacy and safety profile in advanced solid tumors, highlighted by an ORR of 26.5% in its pivotal phase 2 trial in RM-NPC patients, which was comparable to approved PD-1 inhibitors AiRuiKa (camrelizumab) (28.3%) and Tuoyi (toripalimab) (23.9%), the only two domestically developed PD-1 inhibitors approved for 3L+ RM-NPC in China, as demonstrated in the diagram below.

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Moreover, A167 demonstrated a good safety profile in all completed clinical trials, with the types and occurrences of AEs comparable to those of approved PD-(L)1 mAbs. Notably, based on the latest non-head-to-head data publicly available, the incidence of immune-related adverse events (irAEs) to A167 was comparable or lower compared to those of AiRuiKa and Tuoyi, as shown in the table below. These clinical trial results underscore A167’s therapeutic potential as the backbone of our immunotherapy franchise and support A167’s position as the first PD-L1 mAb expected to be approved for treating RM-NPC in China.

	A167 (N = 398)	AiRuiKa (N = 1,520)	Tuoyi (N = 943)
	irAE incidence (%)		
Pneumonia	1.0	4.5	2.5
Hepatitis	1.0	10.5	3.8
Diarrhea or Colitis	0.3	1.3	0.3
Nephritis	0	2.3	0.4
Myocarditis	0.5	0.2	0.3
Myositis	0	0.06	0.2
Pancreatitis	0	1.1	0.5
Skin adverse reactions	4.5	8.8	3.9
Thrombocytopenia	0.8	1.1	1.3
Endocrine abnormalities			
Hypothyroidism	13.6	25.4	14.5
Hyperthyroidism	5.8	7.8	6.4
Thyroiditis	0.3	0.3	0.5
Hypophysitis	0	0.2	N/A
Adrenal insufficiency	0	0.6	0.5
Pituitary insufficiency	0	N/A	0.3
Hyperglycemia and diabetes	0.8	1.9, 0.6 ⁽¹⁾	2.2

Notes:

(1) AiRuiKa’s incidence of hyperglycemia is 1.9% and that of diabetes is 0.6%.

Sources: AiRuiKa: AiRuiKa’s drug label; Tuoyi: Tuoyi’s drug label

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Clinical Development Plan

We are advancing the clinical development of A167 as the backbone of our immunotherapy franchise, both as a monotherapy and combination therapy with our ADCs and other oncology assets. We initiated a phase 1a clinical trial for advanced solid tumors and a pivotal phase 2 trial for RM-NPC in China in December 2017 and January 2019, respectively, and completed these two trials in April 2022 and January 2022, respectively. We are conducting a phase 3 trial of A167 in combination with chemotherapy as a first-line treatment for RM-NPC, as well as two phase 2 trials of A167 in combination with SKB264 for advanced NSCLC (with or without chemotherapy) and advanced TNBC, respectively. The table below sets forth our clinical development plan for A167:

Indication	Mono-/Combo-therapy	Location	Trial phase/designation	Trial status	(Expected) Trial start date	Expected trial end date
RM-NPC	Combo with chemo (cisplatin and gemcitabine)	China	Phase 3	Ongoing	March 2022	2H 2025
Advanced NSCLC	Combo with SKB264 ± platinum-based chemo	China	Phase 2	Ongoing	May 2022	2H 2024
Advanced TNBC	Combo with SKB264	China	Phase 2	Ongoing	July 2022	1H 2025

Summary of Clinical Trial Data

After receiving IND approval in September 2017, we have completed several clinical trials of A167 in China, covering multiple indications including advanced solid tumors and RM-NPC. Set forth below is a summary of the key data from A167’s completed and ongoing clinical trials.

Phase 3 Clinical Trial for RM-NPC

This is a multi-center, double-blind, randomized, placebo-controlled trial to evaluate the safety and efficacy of A167 in combination with cisplatin and gemcitabine as a potential first-line treatment for patients with RM-NPC. This trial plans to enroll 291 patients across 39 clinical research centers in China.

Trial Objectives. The primary endpoint is the IRC-assessed PFS based on RECIST 1.1. The secondary endpoints include the PFS assessed by Investigator Assessment according to RECIST 1.1, the ORR, DCR, DOR and TTR assessed by the IRC and trial investigators based on RECIST 1.1, OS (1-year and 2-year), the levels of ADA before and after drug administration, and the safety and PK of A167.

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Trial Progress. Patient enrollment of this trial had been completed as of the Latest Practicable Date.

Trial Design. Subjects are randomized 2:1 to receive either combinations of 1200 mg of A167, 80 mg/m² of cisplatin and 1000 mg/m² of gemcitabine, or placebo, administered intravenously once every three weeks until there is confirmed disease progression, intolerable toxicity, or withdrawal of informed consent.

Pivotal Phase 2 Clinical Trial for RM-NPC

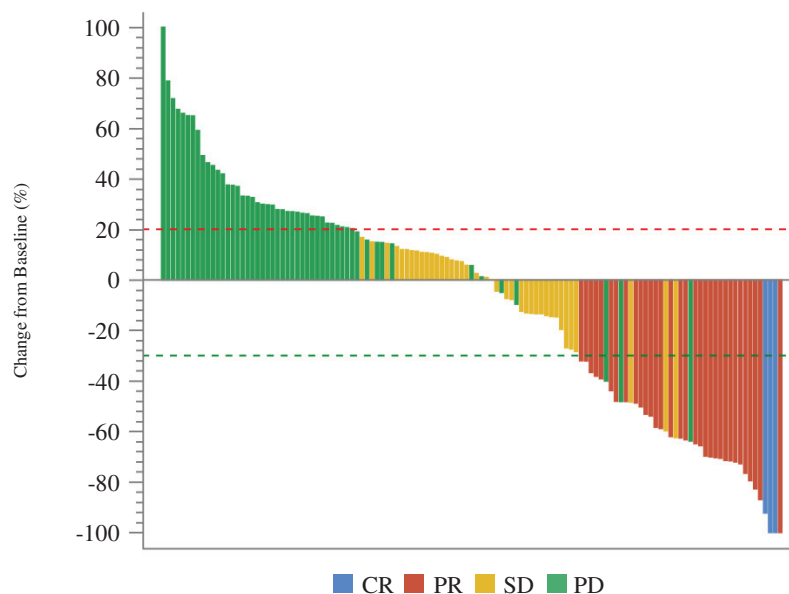
This was an open-label, multi-center, single-arm trial to evaluate the safety and efficacy of A167 in patients with RM-NPC. This trial was conducted in 153 patients across 44 clinical research centers in China.

Trial Objectives. The primary endpoint was the IRC-assessed ORR based on RECIST 1.1. The secondary endpoints were the ORR by Investigator Assessment according to RECIST 1.1 and immune-related response evaluation criteria in solid tumors, PFS, OS, DCR, DOR, TTR, and the PK, immunogenicity, safety of A167.

Trial Progress. This trial was completed in January 2022.

Trial Design. Subjects received 900 mg of A167, administered intravenously once every two weeks until there was confirmed disease progression, intolerable toxicity, or withdrawal of informed consent.

Efficacy Data. A167 elicited an ORR of 26.5% in the 132 patients who had at least one efficacy assessment, among whom three patients had CR, 32 had PR, 40 had SD and 51 had PD, as illustrated in the waterfall plot below. The median PFS, DOR, and OS were 2.8 months, 12.6 months, and 15.3 months, respectively. The below waterfall plot shows the best percentage change from baseline in target lesions for each evaluable patient.



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Safety Data. 115 (75.2%) patients experienced at least one TRAE. The most common ($\geq 10\%$) TRAEs included hypothyroidism (24.8%), anemia (13.1%) and leukopenia (10.5%). Grade 3 or above TRAEs occurred in 24 (15.7%) patients, among which 8 (5.2%) patients experienced treatment-related SAEs. Seventeen (11.1%) patients died due to AEs, which were considered by the trial investigator to be unrelated to the study drug. Four (2.6%) patients experienced study drug-related AEs leading to permanent discontinuation. 32 (20.9%) patients experienced irAEs, of which six (3.9%) patients had grade 3 or higher irAEs.

Conclusion. A167 demonstrated encouraging anti-tumor efficacy in RM-NPC patients with a manageable safety profile.

Phase 1a Clinical Trial for Advanced Solid Tumors

This was an open-label, multi-center, single-arm trial to evaluate the safety and tolerability of A167 in patients with locally advanced or metastatic solid tumors and to determine the RP2D of A167. This trial was conducted in 102 patients across eight clinical research centers across China.

Trial Objectives. The primary endpoints were the safety and tolerability of A167. The secondary endpoints were A167’s PK, receptor occupancy (i.e., the degree of occupancy of A167 on cell-surface PD-L1), immunogenicity, preliminary efficacy, and biomarkers.

Trial Progress. This trial was completed in April 2022.

Trial Design. Subjects received 600, 900, 1,200, 1,500, or 1,800 mg of A167 once every 14 days or once every 21 days until there was confirmed disease progression, intolerable toxicity, or withdrawal of informed consent.

Efficacy Data. A167 demonstrated an ORR of 15.69% and DCR of 60.78% in 102 patients with locally advanced or metastatic solid tumors. The results of the subgroup analyses are shown in the table below:

Subgroup	ORR	DCR
NPC	28.57% (2/7)	71.43% (5/7)
HNSCC	27.27% (3/11)	54.55% (6/11)
CC	25.00% (4/16)	62.50% (10/16)
Liver cancer	13.64% (3/22)	72.73% (16/22)
LC	7.89% (3/38)	55.26% (21/38)

Safety Data. A167 exhibited manageable safety in patients with advanced solid tumors who received an escalating dose of A167 injection up to 1800 mg once every 21 days. 87 (85.3%) patients had at least one TRAE. The most common ($\geq 20\%$ incidence rate) TRAEs were increased blood thyroid stimulating hormone (TSH) (23.5%), increased aspartate aminotransferase (21.6%) and increased alanine aminotransferase (21.6%). Grade 3 or above TRAEs occurred in 17 (16.7%) patients, among which seven patients had treatment-related SAEs. AEs led to death in 11 (10.8%) patients, among which ten patients died due to AEs that were considered by the trial investigator to be unrelated or possibly unrelated to the study drug, while one patient died due to pulmonary inflammation that was considered by the trial investigator to be probably related to the study drug.

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Conclusion. A167 demonstrated encouraging anti-tumor efficacy in a range of advanced solid tumors with a manageable safety profile.

Next Steps

We submitted an NDA to the NMPA for A167 as a 3L+ treatment for RM-NPC in November 2021 based on our pivotal phase 2 trial results, which met the primary endpoint pre-specified by the NMPA, and expect to receive conditional approval in the second half of 2023 or the first half of 2024.

In parallel, we have positioned A167 as the cornerstone for combination therapies with other assets in our pipeline to exploit the potential synergy between immune-oncology and ADC/targeted therapy. We are conducting two phase 2 trials in China to evaluate the combination potential of A167 and SKB264 as a 1L treatment for advanced NSCLC (with or without chemotherapy) and advanced TNBC.

A167 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A140 – An EGFR mAb

Overview

We are developing A140, an EGFR mAb, as a cetuximab biosimilar. Cetuximab, in combination with chemotherapy, is approved by the NMPA for treating mCRC with wild-type RAS, an oncogene, and RM-HNSCC in China. In combination with radiotherapy, cetuximab is also approved in China for treating LA-HNSCC. In 2018, cetuximab was included in the NRDL through price negotiation. Driven by its high demand in China and NRDL inclusion, cetuximab posted annual sales of approximately €441 million in the Asia-Pacific region in 2022. The patent protection for cetuximab in China expired in 2017. While a number of biotech companies in China are developing cetuximab biosimilars, none had been approved as of the Latest Practicable Date.

A140 has the potential to be the first cetuximab biosimilar approved in China, providing increasing accessibility and affordability to an underserved patient population. It demonstrated PK bioequivalence to cetuximab in a phase 1 clinical trial, with a pivotal phase 3 clinical equivalence trial for RAS wild-type mCRC underway. Notably, according to Frost & Sullivan, A140 is the first cetuximab biosimilar candidate in China to adopt a phase 3 head-to-head trial design that strictly follows the CDE’s Guidelines for Design of Clinical Trials of Injectable Cetuximab Biosimilar (for Trial Implementation) (“Cetuximab Biosimilar Guidelines”), which potentially translates into an accelerated review process.

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We plan to file an NDA with the NMPA in the second half of 2023 for RAS wild-type mCRC. With cetuximab in the NRDL, A140, upon its anticipated NMPA approval, is expected to be automatically admitted into the NRDL, potentially facilitating A140’s market penetration as a potential first cetuximab biosimilar. Further, we will follow the CDE’s “Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars” (《生物類似藥相似性評價和適應症外推技術指導原則》) to explore the opportunities of A140 for treating other indications for which cetuximab has been already approved, including RM-HNSCC and LA-HNSCC, as well as indications for which cetuximab is currently under clinical development in China, such as NSCLC.

Background of Reference Drug

Cetuximab was developed by the Weizmann Institute of Science, one of the world’s top-ranking multidisciplinary research institutions. Since its first FDA approval under the brand name Erbitux in 2004, cetuximab in combination with chemotherapy has been approved as an early-line treatment for RAS wild-type, EGFR-expressing mCRC, BRAF V600E-mutated mCRC and RM-HNSCC and in combination with radiotherapy for LA-HNSCC in various countries, including the U.S., EU, and China. Cetuximab is also under clinical trials for other indications across the world, such as NPC, NSCLC and cutaneous squamous cell carcinoma (cSCC). In China, cetuximab was first approved by the NMPA as a 2L treatment for mCRC in 2005. It was then approved as a first-line treatment in combination with chemotherapies for RAS wild-type mCRC in 2019, and in combination with chemotherapies as a first-line treatment for RM-HNSCC in 2020. In 2022, cetuximab, in combination with radiotherapy, was approved by the NMPA as a first-line treatment for LA-HNSCC. According to Frost & Sullivan, the total incidence of RAS wild-type mCRC, RM-HNSCC and LA-HNSCC reached 350.1 thousand in 2022 in China and is expected to reach 422.0 thousand by 2030. In 2018, cetuximab was included in the NRDL through price negotiation with a price of RMB1,295 for a 100 mg (20 ml) vial set. According to Frost & Sullivan, the treatment cost for cetuximab was RMB137.8 thousand in 2022.

Clinical trials combining cetuximab with chemotherapy or radiotherapy have demonstrated marked synergy with significant improvement in anti-tumor activity compared to chemo or radiotherapy alone. For mCRC patients with wild-type Kirsten RAS, an oncogene, adding cetuximab to FOLFIRI chemotherapy significantly improved the ORR from 38.6% to 66.3% and extended the median OS from 20.2 months to 28.4 months compared with FOLFIRI alone. For patients with locally advanced HNSCC, cetuximab plus radiation therapy significantly improved the median OS from 29.3 months to 49.0 months compared to radiation alone. Combining cetuximab with platinum-based chemotherapy for the treatment of RM-HNSCC increased the ORR from 19.5% to 35.6% and prolonged the OS from 7.4 months to 10.1 months compared to platinum-based chemotherapy alone. Patients taking cetuximab usually tolerate the drug well. The most common side effects are skin rashes, low magnesium levels in the blood and allergic reactions due to IV infusion.

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Mechanism of Action

In normal cells, upon the binding of its growth factor ligands, EGFR initiates a series of signaling events, including the activation of RAS family proteins that subsequently activate gene programs responsible for promoting various cell functions, including proliferation, survival, differentiation, and migration. Tumor cells frequently hijack this signaling pathway by overexpressing EGFR, leading to constant activation that fuels tumor cell growth, invasion, and metastasis. Since EGFR is a major oncogenic driver in many cancers, it has become one of the most attractive targets for anti-cancer treatments, with EGFR mAbs being one of the major therapeutic approaches. EGFR mAbs have been shown to be effective against tumors with wild-type RAS gene.

A140 is an EGFR mAb that exerts its anti-tumor effects via several mechanisms. By binding to the extracellular domain of EGFR, A140 blocks ligand binding to the receptor, thereby inhibiting ligand-dependent activation of EGFR and its downstream oncogenic signaling. A140 also downregulates the expression of EGFR by promoting its internalization, a process where EGFR is engulfed within the cell and ultimately degraded. These inhibitory functions induce cell cycle arrest to halt the progression of tumor cell division, decrease the expression of pro-angiogenic factors to suppress tumor cell invasion and metastasis, as well as promote apoptosis, or programmed cell death, in tumor cells by altering the balance of pro/anti-apoptosis factors. In addition to interrupting EGFR signaling, A140 can trigger an immunologic anti-tumor effects such as ADCC), ADCP, CDC and adaptive immunity-mediated by CD8⁺ cytotoxic T cells in which NK cells, macrophages, complement and cytotoxic T cells can recognize and bind to the tumor cells bound with A140, leading to the activation of cytotoxic signaling that kills the tumor cells.

Market Opportunity and Competition

RAS wild-type mCRC. CRC is the third most common cancer and one of the leading causes of cancer mortality in China. Of all the newly diagnosed CRC patients, approximately 20% have metastatic disease at presentation and about 80% with CRC eventually develop metastases. RAS wild-type mCRC accounts for approximately half of all mCRC cases. According to Frost & Sullivan, the incidence of RAS wild-type mCRC in China increased from 173.7 thousand in 2017 to 202.5 thousand in 2022 and is expected to reach 253.6 thousand in 2030.

In China, the treatment paradigm for RAS wild-type mCRC primarily involves combination chemotherapy with cetuximab or anti-angiogenic mAb bevacizumab. Although either cetuximab or bevacizumab can be used in combination with chemotherapy as the first-line treatment, a retrospective trial analysis published in JAMA Oncology shows that cetuximab in combination with chemotherapy regimen has a better ORR and OS compared with bevacizumab in combination with chemotherapy regimen for treating RAS wild-type mCRC patients with left-sided tumors.

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HNSCC. HNSCC is a prevalent and deadly cancer that occurs in the mucous membranes of mouth, nose, and throat. Over 90% of head and neck tumors is HNSCC. LA-HNSCC and RM-HNSCC account for approximately 60% and 50% of all HNSCC cases, respectively. According to Frost & Sullivan, the incidence of LA-HNSCC in China increased from 72.4 thousand in 2017 to 80.5 thousand in 2022 and is forecasted to reach 91.9 thousand in 2030. The incidence of RM-HNSCC in China increased from 60.3 thousand in 2017 to 67.1 thousand in 2022 and is expected to reach 76.6 thousand in 2030.

In China, the current treatment paradigm of LA-HNSCC comprises surgery, radiotherapy, platinum-based chemotherapy and targeted therapy. First-line treatment options include surgery with or without radiotherapy or radiochemotherapy, radiotherapy in combination with platinum-based chemotherapy, and induction chemotherapy followed by radiotherapy, with cetuximab in combination with radiotherapy available in the 2L setting. For RM-HNSCC, PD-1 mAb monotherapy and doublet chemotherapy in combination with cetuximab represent the first-line treatment options, with PD-1 inhibitor nivolumab as monotherapy in the 2L setting. Compared with PD-1 mAb Keytruda as a monotherapy, doublet chemotherapy in combination with cetuximab demonstrated greater therapeutic benefits in terms of median PFS (5.0 months with cetuximab plus chemotherapy, 3.2 months with Keytruda) and ORR (35.0% with cetuximab plus chemotherapy, 19.0% with Keytruda).

Despite the competition, the demand for cetuximab is increasing, especially after it was included in the NRDL in 2018. However, cetuximab still commands a high cost with approximately RMB11,000 per month in 2022. The high cost of cetuximab posts substantial financial burdens on patients and health insurance providers, indicating a substantial unmet need for cetuximab biosimilars to improve drug affordability. Although a number of biotech companies in China are developing cetuximab biosimilars, none had been approved as of the Latest Practicable Date. As of the Latest Practicable Date, there were six cetuximab biosimilar candidates in phase 1 or beyond in China, with three of them in phase 3. For details, see “Industry Overview – China’s EGFR mAb Market – Competitive Landscape of EGFR mAbs.”

Summary of Clinical Trial Data

Following CDE’s guidelines, we initiated a phase 1 clinical trial in China in January 2017 to demonstrate PK bioequivalence of A140 to cetuximab and completed this trial in September 2017. As phase 2 trial is not required for biosimilars, we commenced a pivotal phase 3 clinical trial in China in December 2020. Set forth below is a summary of the key data from A140’s completed and ongoing clinical trials.

Pivotal Phase 3 Clinical Trial for RAS wild-type mCRC in combination with mFOLFOX6

This is a double-blind, randomized, multi-center head-to-head trial to evaluate A140’s efficacy and safety versus cetuximab as a 1L treatment in combination with mFOLFOX6 chemotherapy regimen for treating RAS wild-type mCRC. This trial plans to enroll 686 subjects in about 80 clinical research centers in China.

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Trial Objectives. The primary endpoint is the study drugs’ ORR by week 16 in accordance with RECIST 1.1. The secondary endpoints include ORR by week 16 assessed by trial investigators, DCR, DOR, PFS, OS, safety of A140 and cetuximab and the correlation between ADA and plasma concentration of the study drugs.

Trial Progress. As of the Latest Practicable Date, this trial was ongoing with patient enrollment completed in November 2022.

Trial Design. The trial consists of two stages, the double-blind stage and the single-arm stage. In the double-blind stage, subjects are randomized 1:1 to receive mFOLFOX6 plus either A140 or cetuximab at 400 mg/m² for 2 hours ± 10 minutes for the first week and 250 mg/m² weekly maintenance for subsequent weeks. In the single-arm stage, the subjects who have benefitted from double-blind study treatment as adjudicated by trial investigators continue to receive A140-mFOLFOX6 treatment until disease progression, intolerable toxicity, or patient/investigator’s decision to withdraw.

Phase 1 Clinical Trial in Chinese Healthy Subjects

This was a single-center, double-blind and randomized trial to evaluate the similarity of PK profiles of A140 and cetuximab among Chinese healthy males. This trial was conducted in 82 subjects in one clinical research center in China.

Trial Objectives. The primary endpoint was A140’s AUC from drug administration to the end of the dosing period (AUC_{0-t}), a PK parameter that describes the observed drug exposure. The secondary endpoints were additional PK parameters, as well as safety and immunogenicity of A140.

Trial Progress. This trial was completed in September 2017.

Trial Design. Subjects were enrolled for 6 months and divided into 2 cohorts. 41 subjects received 250 mg/m² of A140 (2 mg/ml) and 41 subjects received 250 mg/m² of cetuximab (5 mg/ml) for two hours.

PK Data. A140 demonstrated PK bioequivalence to cetuximab, as demonstrated in the table below that the 90% confidential intervals (CIs) for the geometric mean ratios of three PK measures, AUC_{0-t}, AUC_{0-∞} and C_{max}, of each cohort fell within the 80%~125% equivalence margin, as set forth in the “Technical Guidelines for Human Bioequivalence Study of Chemical Drug Biosimilar with Pharmacokinetic Parameters as Endpoint Evaluation Indicators 《以藥動學參數為終點評價指標的化學藥物仿製藥人體生物等效性研究技術指導原則》)” issued by the NMPA.

Pharmacokinetic parameters (unit)	Geometric mean and ratio			CV (coefficient of variation) %	90% CI
	A140	Cetuximab	(A140/Cetuximab) %		
C _{max} (µg/ml) ¹	158.49	169.82	95%	13.59%	89%~100%
AUC _{0-t} (hr*µg/ml) ²	11,220.18	10,715.19	105%	18.86%	98%~112%
AUC _{0-∞} (hr*µg/ml) ³	11,220.18	10,964.78	105%	18.64%	98%~112%

Notes:

- (1) C_{max}: maximum drug concentration in plasma;

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- (2) $AUC_{0,t}$: AUC from drug administration to the end of the dosing period;
- (3) $AUC_{0,\infty}$: AUC from drug administration to the time that the drug is no longer present in the subject’s body.

Safety Data. There was no observable difference in safety profiles between A140 and cetuximab.

Immunogenicity Data. A140 demonstrated an immunogenicity profile similar to that of cetuximab. The incidence of ADA formulation was detected as 7.5% in both cohorts, of which the PK features show no obvious difference among ADA-positive and ADA-negative subjects.

Conclusion. A140 demonstrated PK bioequivalence and a similar safety and immunogenicity profile to cetuximab.

Next Steps

We expect to complete our pivotal phase 3 clinical trial of A140 in China in the second half of 2023 and file an NDA with the NMPA for RAS wild-type mCRC in the second half of 2023. Further, we will follow the CDE’s “Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars” (《生物類似藥相似性評價和適應症外推技術指導原則》) to explore the opportunities of A140 for treating other indications for which cetuximab has been already approved, including RM-HNSCC and LA-HNSCC, as well as indications for which cetuximab is currently under clinical development in China, such as NSCLC and cSCC.

A140 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A400 – A Second-generation Selective RET Inhibitor

Overview

A400 is positioned to be the first domestically developed second-generation selective RET inhibitor for treating RET+ solid tumors in China. RET alterations have been reported to be a major oncogenic driver in about 2% of all cancers, most notably in NSCLC and MTC. Although two first-generation selective RET inhibitors were approved in China for RET+ solid tumors as of the Latest Practicable Date, their therapeutic benefits are limited, in part, by acquired RET drug-resistant mutations and safety issues such as hypertension and hematological toxicity, underscoring the need for novel selective RET inhibitors with improved safety and better efficacy against drug resistant mutations. A400 is designed with a novel proprietary molecular structure to address selective RET inhibitor resistance while maintaining target selectivity, efficacy and safety with reduced manufacturing cost and difficulty. Building upon its strong potency against diverse RET alterations and CNS penetration demonstrated in preclinical studies, A400 showed promising anti-tumor efficacy in patients with advanced RET+ solid tumors, highlighted by ORR of 74% and 66.7% at RP2D for first-line and 2L+ advanced RET+ NSCLC, respectively, based on preliminary results from its ongoing phase 1/2

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trial. Notably, A400 also demonstrated therapeutic potential in selective RET inhibitor-resistant patients with an ORR of 33% and DCR of 83% at RP2D, as well as a differentiated safety profile, with no incidence of grade 3 or above lymphopenia and thrombocytopenia and substantially lower incidence of grade 3 or above cardiovascular AEs (e.g., hypertension), hematological toxicity and electrolyte abnormalities, based on non-head-to-head cross-trial comparisons with approved selective RET inhibitors. These encouraging results support the potential of A400 to be an efficacious and safe second-generation selective RET inhibitor for NSCLC, MTC and other solid tumors with a high prevalence of RET alterations.

We are rapidly progressing the clinical development of A400 in China. We completed the dose escalation study of a phase 1/2 trial for advanced RET+ solid tumors with ongoing patient enrollment for the dose expansion study. Based on the promising preliminary results of A400 in both first-line and 2L+ advanced RET+ NSCLC patients, we completed CDE clinical consultation and initiated a pivotal trial for 2L+ advanced RET+ NSCLC in May 2023. Moreover, we plan to commence a pivotal trial for 1L advanced RET+ NSCLC in the second half of 2023 and a pivotal trial for advanced RET+ MTC in the first half of 2024. For details, see “– Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A400 – Clinical Development Plan.”

Mechanism of Action

The RET gene is a proto-oncogene, a gene that promotes cancer formation when altered by mutations or rearrangements. In normal conditions, it encodes the RET transmembrane receptor tyrosine kinase, an enzyme-linked receptor that exists across a cell membrane with important functions in organ development. However, gene mutations and fusions that occur on the RET gene can result in a mutant RET protein that becomes active in the absence of a ligand. Mutant RET drives the hyperactivation of downstream signalling pathways, leading to uncontrollable cell growth and tumor formation. Given the key role of altered RET in driving cancer development, RET-targeting therapies have been a promising approach to treat RET+ cancers.

A400 is engineered to provide specific RET pathway inhibition with potentially greater efficacy, through comprehensive analysis of the key chemical groups and clinical manifestations of first-generation selective RET inhibitors Gavreto (pralsetinib) and Retevmo (selpercatinib), the only two FDA and NMPA-approved selective RET inhibitors as of the Latest Practicable Date. It possesses nanomolar potency against diverse RET alterations, including certain mutations that mediate resistance to existing selective RET inhibitors. A400's binding to RET suppresses RET's enzymatic activity in RET+ cancers, thereby interrupting RET-mediated oncogenic signal. The pharmacological properties of A400 were also optimized to facilitate CNS penetration, which potentially allows A400 to effectively treat brain metastases, a common complication of RET+ solid tumors.

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Market Opportunity and Competition

RET alterations have been found in about 2% of cancers, most prominently in NSCLC and MTC, the first two indications that A400 is designed to target.

RET+ NSCLC. NSCLC accounts for over 85% of LC, which is the second most common cancer and the leading cause of cancer death globally. RET+ NSCLC amounts to approximately 1-2% of total NSCLC cases. According to Frost & Sullivan, the incidence of RET+ NSCLC in China grew from 13.6 thousand in 2017 to 15.9 thousand in 2022 and is expected to reach 20.0 thousand in 2030.

In China, the first-line treatment options largely follow treatment guidelines recommended for driver mutation-negative advanced NSCLC, which involves chemoimmunotherapy with or without anti-angiogenic mAb bevacizumab and monotherapy with PD-L1 inhibitor for PD-L1+ patients, with the addition of first-generation selective RET inhibitor Retevmo as another first-line option. The 2L+ treatment options include single-agent chemotherapy, doublet chemotherapy with or without bevacizumab, PD-1 inhibitor monotherapy, and first-generation selective RET inhibitors Gavreto and Retevmo (for patients who have not received first-line targeted therapy).

Although both first-generation selective RET inhibitors demonstrated robust initial treatment responses, their therapeutic benefits are limited by RET drug-resistant mutations acquired during the treatment course, as well as safety issues such as hypertension and hematological toxicity, necessitating the development of novel selective RET inhibitors with improved safety and better efficacy against mutations that confer selective RET inhibitor resistance. As of the Latest Practicable Date, according to Frost & Sullivan, Gavreto and Retevmo were the only selective RET inhibitors approved for the treatment of advanced RET+ NSCLC in China, and there were four selective RET inhibitor candidates in phase 1/2 or beyond for RET+ NSCLC in China. For details regarding the competitive landscape of selective RET inhibitors in China, see “Industry Overview – China’s Selective RET Inhibitor Market – Competitive Landscape of Selective RET Inhibitors.”

RET+ MTC. TC is the most common type of endocrine cancers. According to studies published in *The Lancet Diabetes & Endocrinology*, it was the fastest growing cancer in China in recent years. MTC accounts for approximately 3% of total TC cases. RET mutations represent a major driver of MTC, occurring in about 90% of MTCs, and are associated with advanced disease and worse clinical outcome. According to Frost & Sullivan, the incidence of RET+ MTC in China increased from 5.6 thousand in 2017 to 6.2 thousand in 2022 and is expected to increase to 7.4 thousand in 2030.

The standard treatments for advanced MTC in China include Gavreto in the first-line setting and Retevmo in the 2L setting.

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Despite the initially promising treatment responses to Gavreto and Retevmo, many patients eventually progress as their tumors acquire RET mutations that confer resistance to these two RET inhibitors. Moreover, Retevmo and Gavreto are associated with safety issues such as hypertension and hematological toxicity that limit their clinical use. This indicates a significant unmet need for novel selective RET inhibitors with improved safety and better efficacy against RET drug-resistant mutations that confer selective RET inhibitor resistance. As of the Latest Practicable Date, according to Frost & Sullivan, Gavreto and Retevmo were the only selective RET inhibitors approved for the treatment of advanced RET+ MTC in China, and there were three selective RET inhibitor candidates in phase 1/2 or beyond for advanced RET+ MTC in China. For details regarding the competitive landscape of selective RET inhibitors in China, see “Industry Overview – China’s Selective RET Inhibitor Market – Competitive Landscape of Selective RET Inhibitors.”

Competitive Advantages

Promising Anti-tumor Efficacy with potential to overcome first-generation selective RET inhibitor resistance. Based on preliminary clinical data from its phase 1/2 trial, A400 demonstrated promising efficacy in patients with advanced RET+ solid tumors, highlighted by ORR of 74% and 66.7% at RP2D (90 mg) for 1L and 2L+ advanced RET+ NSCLC, respectively. According to the latest non-head-to-head data publicly available, the preliminary ORRs demonstrated by A400 against advanced RET+ NSCLC in both 1L patients and selective RET inhibitor-naïve 2L+ patients are comparable or better than those of first-generation selective RET inhibitors Gavreto and Retevmo, as illustrated in the diagram below.

Drug name (Dosage)	A400 (90 mg QD)				Gavreto (400 mg QD)		Retevmo (160 mg BID)	
	1L	SRI-naïve	2L+ SRI-resistant	Overall	1L	2L+ SRI-naïve	1L	2L+ SRI-naïve
Patient number	19	15	6	21	27	87	39	105
ORR	74%	80%	33%	66.7%	70%	57%	85%	64%
DCR	100%	93%	83%	90.5%	85%	91%	95%	93%

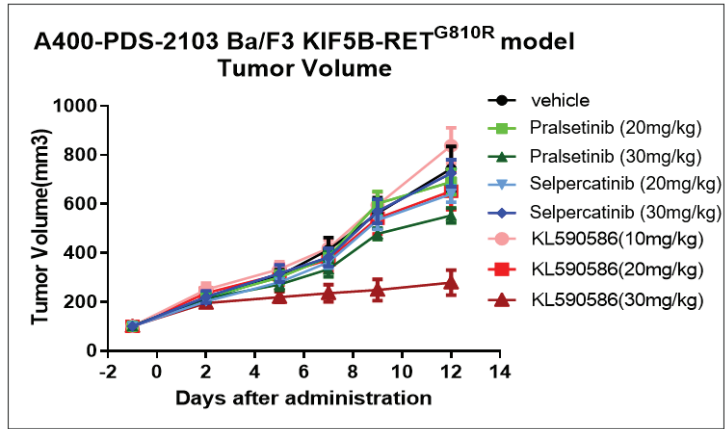
Note:

(1) SRI refers to selective RET inhibitor.

Sources: Gavreto: Gavreto’s drug label; Retevmo: Retevmo’s drug label

Notably, designed with a novel proprietary molecular structure to address selective RET inhibitor resistance, A400 demonstrated promising clinical efficacy in selective RET inhibitor-resistant patients, including seven patients (six RET+ NSCLC, one RET+ MTC) who had prior first-generation selective RET inhibitor Gavreto, with an ORR of 33% and a DCR of 83% at RP2D, based on preliminary clinical data from its phase 1/2 trial. These encouraging results are consistent with the findings from our head-to-head preclinical studies. As demonstrated in the diagram below, A400 demonstrated greater TGI in an *in vivo* drug-resistant (RET G810R mutation) xenograft model, compared with Gavreto (pralsetinib) and Retevmo (selpercatinib) at the same dose. Altogether, these clinical and preclinical results support the promising anti-tumor efficacy potential of A400 for treating 1L, 2L+ and selective RET inhibitor-resistant patients with advanced RET+ solid tumor.

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Differentiated Safety Profile. A400 showed a differentiated safety profile based on preliminary results from its phase 1/2 trial, where most reported AEs were mild or moderate. As shown in the table below, compared with the two approved first-generation selective RET inhibitors, A400 demonstrated no incidence of grade 3 or above lymphopenia and thrombocytopenia and substantially lower incidence of grade 3 or above cardiovascular AEs (e.g., hypertension), hematological toxicity and electrolyte abnormalities. Although no head-to-head data are available at this stage, we believe these comparisons below indicate the differentiated features and advantages of A400 from a safety perspective.

Grade 3 or above TRAEs for A400, Retevmo and Gavreto⁽¹⁾

Preferred term	A400 90 mg QD	Retevmo 160 mg BID	Gavreto 400 mg QD
	(N=53)	(N=796)	(N=220)
	Incidence (%)		
Elevated AST level	1.1	11	2.3
Elevated ALT level	1.1	12	2.3
Anemia	0	3.5	9
Hypocalcemia	0	5.7	1.8
Lymphopenia	0	20	19
Hyponatremia	0	11	7
Phosphate reduction	0	N/A	11
Neutropenia	0	3.2	16
Diarrhea	0	5	3.2
Hypertension	0	20	14
Infectious			
Pneumonia	1.1	N/A	8

Note:

(1) This table summarizes the grade 3 or above TRAEs with an incidence of ≥ 5% for A400, Retevmo, or Gavreto.

Sources: Gavreto: Gavreto’s drug label; Retevmo: Retevmo’s drug label

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Clinical Development Plan

We are rapidly progressing the clinical development of A400 in China. Following A400’s IND approval in June 2021, we initiated a phase 1/2 clinical trial in patients with advanced RET+ solid tumors in July 2021.

Based on the promising preliminary results of A400 in 1L and 2L+ advanced RET+ NSCLC patients, we completed CDE clinical consultation and initiated a pivotal trial for 2L+ advanced RET+ NSCLC in May 2023. We expect to commence a pivotal trial for 1L advanced RET+ NSCLC in the second half of 2023. Moreover, we plan to initiate a pivotal trial in the first half of 2024 to advance the development of A400 for advanced RET+ MTC.

The table below sets forth our clinical development plan for A400:

Indication (Lines of Treatment)	Trial phase	Trial status	(Expected) Trial start date	Expected trial end date	Location
Advanced RET+ NSCLC (1L)	Pivotal	CDE clinical consultation completed	(2H 2023)	2H 2026	China
Advanced RET+ NSCLC (2L+)	Pivotal	Ongoing	May 2023	1H 2026	China
Advanced RET+ MTC	Pivotal	In planning	(1H 2024)	1H 2027	China
Adjuvant or neoadjuvant RET+ NSCLC	Phase 2	In planning	Pending	N/A	China
Advanced RET+ solid tumors ⁽¹⁾	Phase 1/2	Completed: dose escalation Ongoing: dose expansion	July 2021	1H 2024	China

Note:

- (1) Including NSCLC, MTC and other selective RET inhibitor-naïve solid tumors, and selective RET inhibitor-resistant solid tumors.

Summary of Clinical Trial Data

We are evaluating A400 in a phase 1/2 clinical trial for advanced RET+ solid tumors. Set forth below is a summary of the key data from A400’s ongoing clinical trial.

Phase 1/2 Clinical Trial for Advanced RET+ Solid Tumors

This is an open-label, multi-center, single-arm phase 1/2 trial to evaluate the safety, tolerability, MTD and RP2D of A400 in patients with advanced RET+ solid tumors. This trial plans to enroll 414 adult subjects.

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Trial Objectives. The primary endpoints of phase 1 include the safety and tolerability of A400 in patients with advanced RET+ solid tumors, and to determine the MTD and RP2D. The primary endpoint of phase 2 is the IRC-assessed ORR. The secondary endpoints include the ORR assessed by Investigator Assessment according to RECIST 1.1 or Response Assessment in Neuro-Oncology (RANO), and the DOR, TTR, DCR, PFS, CNS ORR and CNS DOR assessed by the IRC and trial investigators. All efficacy parameters are assessed based on RECIST 1.1 or RANO.

Trial Progress. Dose escalation was completed in November 2022, with 19 patients enrolled and dosed at 10 mg (n=1), 20 mg (n=3), 40 mg (n=3), 60 mg (n=3), 90 mg (n=6) and 120 mg (n=3) once daily. As of December 30, 2022, patient enrollment for the dose expansion cohort was ongoing, with 87 patients enrolled and dosed at 10 mg, 20 mg, 40 mg, 60 mg, 90 mg or 120 mg once daily.

Trial Design. This study is divided into phase 1 and phase 2. Phase 1 was a dose escalation and dose expansion study in which subjects received 10, 20, 40, 60, 90, or 120 mg of oral A400 capsule once daily until disease progression, intolerable toxicity, death, or other treatment termination criteria are met. In phase 2, subjects are assigned into different cohorts based on their respective types of RET+ tumors to receive A400 at RP2D for cycles of 28 days until disease progression, intolerable toxicity, death or other treatment termination criteria are met.

Efficacy Data.

RET+ NSCLC. Clinical responses were observed from 40 mg onwards. As of the data cut-off date (December 30, 2022), 57 patients were evaluable for response assessment. The ORRs and DCRs of the 57 evaluable patients across 40, 60, 90 and 120 mg A400 cohorts are illustrated in the diagram below. In the 4 1L patients with measurable brain metastases, the brain metastasis ORR was 75.0% (3/4) and brain metastasis DCR was 100% (4/4).

Patient group	40 mg		60 mg		90 mg (RP2D)		120 mg		Overall						
	1L	2L+	1L	2L+	1L	2L+	1L	2L+	1L	2L+					
	SRI-naïve	SRI-resistant	SRI-naïve	SRI-resistant	SRI-naïve	SRI-resistant	SRI-naïve	SRI-resistant	SRI-naïve	SRI-resistant					
Patient number	0	2	0	4	1	19	15	6	2	2	25	23	9		
ORR	0%	50%	0	100%	50%	0	74%	80%	33%	50%	100%	50%	76%	74%	33%
DCR	0%	100%	0	100%	100%	0	100%	93%	83%	50%	100%	100%	92%	96%	78%

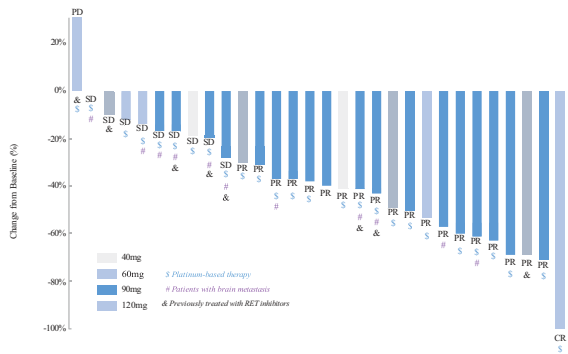
Note:

- (1) SRI refers to selective RET inhibitor.

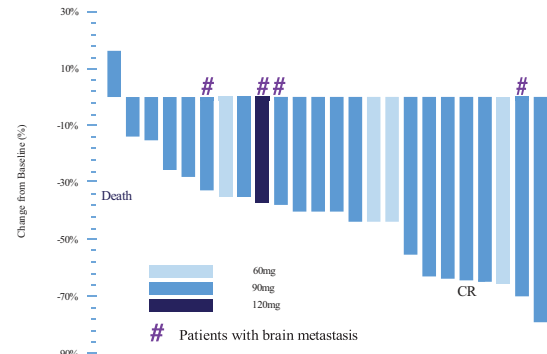
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The below waterfall plots show the best percentage change from baseline in target lesions for each evaluable patient.

Best percentage change in the diameter sum of target lesions of 2L+ RET+ NSCLC patients from baseline

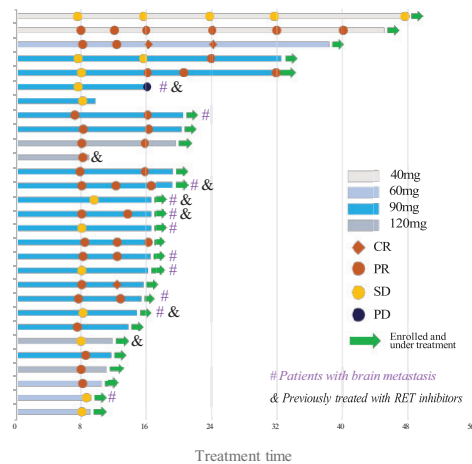


Best percentage change in the diameter sum of target lesions of 1L RET+ NSCLC patients from baseline

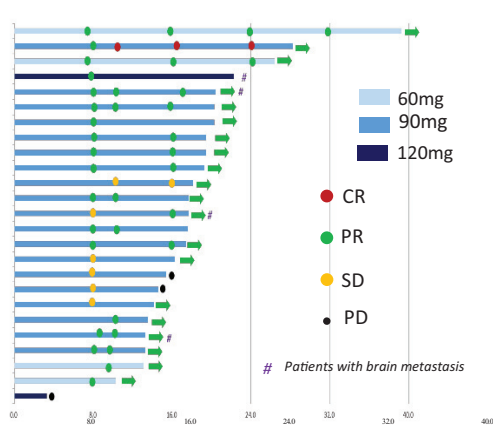


The swimmer plots below show the durable objective responses and disease stabilization of the evaluable patients with SD, PR and CR.

Swimmer plot of 2L+ RET+ NSCLC patients with SD/PR/CR



Swimmer plot of 1L RET+ NSCLC patients



Other RET+ indications. Although the data was not mature, potential efficacy of A400 was observed in patients with advanced RET+ MTC, advanced RET+ PC and advanced RET+ OC.

Safety Data. As of the data cut-off date (December 30, 2022), of 87 patients evaluable for safety assessment, TRAEs were reported in 81 (93.1%) patients. Most TRAEs were grade 1 or 2, and recovered after safety monitoring, dose modification and corresponding treatment. Grade 3 or above TRAEs were reported in 21 (24.1%) patients. The table below summarizes the TRAEs with an incidence of > 15% across the A400 10, 20, 40, 60, 90 and 120 mg cohorts.

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Preferred term	A400 (10-20-40-60-90-120mg, QD)	
	(N=87), n (%)	
	All grades (%)	>Grade 3 (%)
At least one TRAE	81 (93.1)	21 (24.1)
Elevated AST level	44 (50.6)	1 (1.1)
Elevated ALT level	42 (48.3)	1 (1.1)
Elevated blood creatinine	29 (33.3)	0
Elevated blood bilirubin	28 (32.2)	0
Constipation	28 (32.2)	0
Headache	27 (31.0)	1 (1.1)
Hypoesthesia	19 (21.8)	0
Elevated blood creatine phosphokinase	18 (20.7)	1 (1.1)
Urinary retention	18 (20.7)	0
Anemia	17 (19.5)	1 (1.1)
Hyperuricemia	17 (19.5)	0
Dizziness	15 (17.2)	1 (1.1)
Blurred vision	15 (17.2)	
Elevated blood alkaline phosphatase	14 (16.1)	2 (2.3)

PK Data. Consistent with preclinical findings, A400 exhibited a longer human half-life and higher plasma exposure than Gavreto and Retevmo in non-head-to-head, cross-trial comparisons.

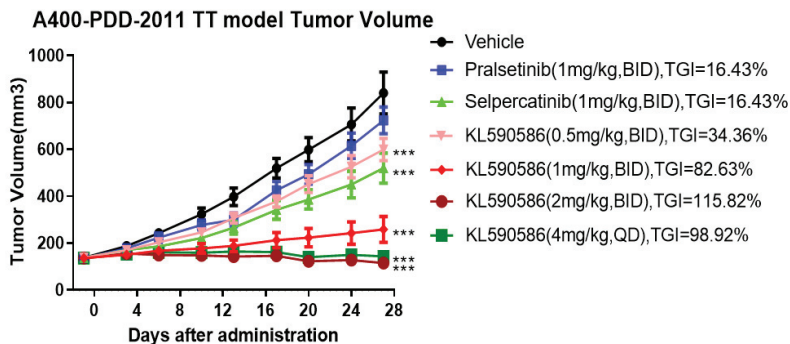
Conclusion. Based on preliminary clinical data, A400 demonstrated a differentiated safety profile and promising anti-tumor activity across a range of advanced RET+ solid tumors with potential for treating brain metastasis and drug-resistant patients.

Summary of Preclinical Data

We have conducted a series of *in vitro* and *in vivo* studies to evaluate A400’s efficacy, CNS penetration, and potency against drug resistance mutations.

The efficacy of A400, under the drug code of KL590586, was studied in a RET-driven MTC cell line-derived xenograft model with RET^{C634W} mutation, head-to-head against pralsetinib and selpercatinib. As shown in the diagram below, A400 demonstrated a dose-dependent anti-tumor effect, measured by percent of TGI, starting from a dose of 0.5 mg/kg administered twice daily. At the same dose (1 mg/kg), A400 achieved an approximately five-fold and a near two-fold higher TGI than pralsetinib and selpercatinib, respectively, at 28 days after treatment initiation.

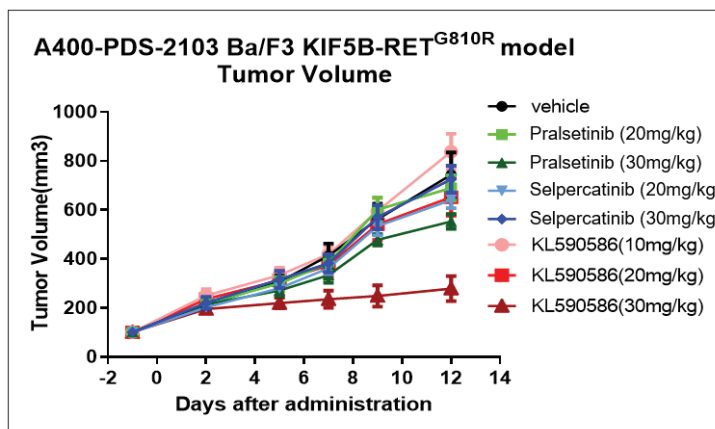
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The potency of A400 against drug resistance mutations was assessed in human Ba/F3 cell line engineered to overexpress human KIF5B-RET fusion protein (Ba/F3-KIF5B-RET) that carries G810R/S/C mutations, alongside Gavreto and Retevmo. As shown in the table below, A400 demonstrated a higher potency against G810R/S/C mutations in the Ba/F3-KIF5B-RET cell line than pralsetinib and selpercatinib, indicated by its lower IC₅₀ values. In line with this result, A400 demonstrated greater TGI in an *in vivo* drug-resistant (RET G810R mutation) xenograft model, compared with pralsetinib and selpercatinib at the same dose, as demonstrated in the diagram below.

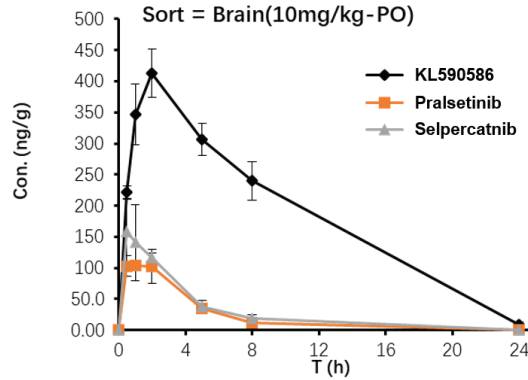
Enzyme Activity – Compound IC ₅₀ (nM)			
Molecular target	Pralsetinib	Selpercatinib	KL590586
RET ^{G810R}	168.45±0.45	73.97±16.40	19.62±0.67
RET ^{G810S}	1.77±0.27	5.66±0.22	2.69±0.56
RET ^{G810C}	48.81±3.82	151.30±30.70	53.16±10.67

Cell Growth Inhibition Activity – Compound IC ₅₀ (nM)			
Cell line	Pralsetinib	Selpercatinib	KL590586
Ba/F3-KIF5B-RET ^{G810R}	181.50±80.02	116.20±1.15	26.25±5.76
Ba/F3-KIF5B-RET ^{G810S}	28.97±4.47	87.89±0.75	20.19±0.35
Ba/F3-KIF5B-RET ^{G810C}	146.40±3.40	477.10±4.40	65.35±1.00



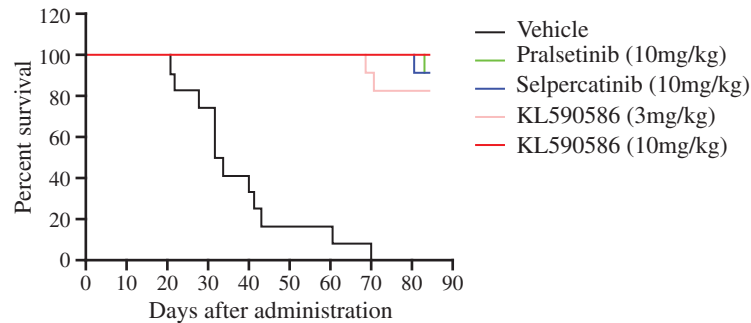
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In head-to-head *in vivo* brain penetration studies, A400 exhibited a higher exposure in the brain compared to pralsetinib and selpercatinib, as illustrated below by the concentration-time curves of these three drugs in the brain.



In line with its greater brain penetration, A400 prolonged the survival of intracranial tumor xenograft mice, i.e., a mouse model of brain metastasis using a RET+ cell line derived from human brain metastatic tumors, in head-to-head comparisons with pralsetinib and selpercatinib as illustrated in the diagram below. Together, these results suggest that A400 has a superior brain penetration and efficacy against brain metastasis compared to the two FDA-approved RET inhibitors.

Increased Survival Rate in Intracranial Tumor Xenograft Following KL590586 Treatment



Next Steps

We plan to initiate a pivotal trial for 1L advanced RET+ NSCLC in the second half of 2023 and a pivotal trial in the first half of 2024 for advanced RET+ MTC. For details, see “– Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – A400 – Clinical Development Plan.”

BUSINESS

A400 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB337 – A PD-L1 and CTLA-4 BsAb

SKB337 is a differentiated PD-L1/CTLA-4 bsAb designed to provide dual blockade of PD-L1 and CTLA-4, two clinically validated immune checkpoints for treating solid tumors. Despite their unprecedented effectiveness, the survival benefits offered by existing immune checkpoint inhibitors as monotherapies are only limited to a minority of cancer patients, whereas the increased efficacy of dual immune checkpoint blockade using a PD-1 mAb and a CTLA-4 mAb comes with severe toxicity and substantial treatment cost. Consequently, there is a significant unmet need for novel approaches that can provide effective concurrent blockade of the PD-(L)1 and CTLA-4 pathways with reduced toxicity and better affordability. With the capability to simultaneously target two antigens on different cell types, bsAb-based therapies represent a promising strategy to provide dual immune checkpoint blockade with improved safety, cost-effectiveness and ease of dosing, supported by the recent NMPA approval of the first and only PD-1/CTLA-4 bsAb Kaitanni (cadonilimab) for relapsed or metastatic cervical cancer.

SKB337 is designed to exploit the differences in timing, location and non-overlapping immune-inhibitory effects mediated by CTLA-4 and PD-L1. It potentially invigorates anti-tumor immunity via the following synergistic mechanisms: (i) promote the expansion and migration of activated T cells to the tumor site by blocking CTLA-4 on T cell surface during the priming phase, (ii) relieve T cells from CTLA-4 and PD-(L)1-mediated inhibition by blocking CTLA-4 on regulatory T cells (Tregs) and PD-L1 on tumor cells and immunosuppressive antigen-presenting cells (APCs), and (iii) deplete Tregs via ADCC and antibody-dependent cell-mediated phagocytosis (ADCP), in which NK cells and macrophages, respectively, are induced by the Fc region of SKB337 to eliminate the SKB337-bound Tregs.

As of the Latest Practicable Date, Kaitanni was the only approved PD-(L)1/CTLA-4 bsAb in China. Including SKB337, there were five PD-(L)1/CTLA-4 bsAbs in phase 1 or beyond in China as of the same date.

In light of the risk of immune-related adverse effects historically associated with CTLA-4 blockade, we specifically designed SKB337 to have a higher affinity for PD-L1 compared to CTLA-4. Given that PD-L1 is frequently overexpressed on tumor cells and immunosuppressive cells in the tumor microenvironment, our differentiated design potentially enriches SKB337 in the tumor site and reduces off-tumor toxicity associated with CTLA-4 blockade.

We received IND approval in February 2021 from the NMPA. We are evaluating SKB337 in a phase 1 dose escalation trial in patients with advanced solid tumors in China, which we initiated in May 2021 and expect to complete in the second half of 2023.

BUSINESS

SKB337 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A289 – A LAG-3 mAb

A289 is a LAG-3 mAb designed to inhibit LAG-3, a new-generation immune checkpoint receptor used by tumor cells to evade immune attacks, for treating solid tumors. To date, the majority of approved immune checkpoint inhibitors target the PD-(L)1 checkpoint. While these PD-(L)1 inhibitors have been paradigm-shifting in various cancer indications, drug resistance limits treatment benefits to only a fraction of cancer patients. Consequently, there is a substantial unmet need for novel inhibitors that target alternative immune checkpoints. LAG-3 is an immune checkpoint receptor highly expressed in various types of immune cells. Based on published studies, it is closely associated with the tumor microenvironment and synergizes with PD-1 in inhibiting anti-tumor immune response. Consequently, LAG-3 has become a foremost target for developing novel single-agent and combination immunotherapy, with its therapeutic potential supported by the recent FDA approval of Opdualag (relatlimab), the first and only FDA-approved LAG-3 inhibitor to date, for treating metastatic melanoma in combination with a PD-1 inhibitor.

For details regarding the incidence of solid tumors in China, see “– Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – SKB337.” As of the Latest Practicable Date, there were no anti-LAG-3 drugs approved in China. According to Frost & Sullivan, there were 15 anti-LAG-3 therapies, either as a single agent or in combination with PD-1 mAb or chemotherapy, in phase 1 or beyond in China as of the Latest Practicable Date, with ten LAG-3 mAbs, four LAG-3/PD-(L)1 bsAbs and one LAG-3/TIGIT bsAb. As of the same date, most anti-LAG-3 drug candidates, including A289, were in phase 1 or phase 2 stage.

Leveraging our extensive mAb platform, the development of A289 underwent an extensive antibody screening and optimization process that led to the identification of a novel human LAG-3 mAb with favorable antigen affinity, antigen specificity and thermal stability compared to relatlimab. Further, we also introduced specific mutations (L234A, L235A and G237A) into the antibody heavy chain to abolish cytotoxic ADCC and CDC functions, thereby reducing the potential of A289 to cause unwanted immune-mediated side effects.

We received IND approval from the NMPA in August 2020 and are conducting a phase 1a/1b clinical trial to evaluate A289 in patients with advanced solid tumors in China, which we initiated in May 2021 and expect to complete in the first half of 2023.

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A289 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A296 – A Novel Second-generation Small Molecule STING Agonist

A296 is a novel second-generation small molecule STING agonist designed with a novel non-CDN hybrid bimolecular structure for treating solid tumors. Currently, immunotherapy relies primarily on immune checkpoint inhibition, which has limited effects on cold tumors, i.e., tumors with inadequate preexisting anti-tumor immunity, signifying a significant unmet need for novel immunotherapy to turn cold tumors hot.

STING is a pattern recognition receptor with a central role in activating immunity by mediating a pro-inflammatory type-I interferon (IFN-I) response. It can be activated in response to DNA in the form of cyclic dinucleotides (CDNs), which are compounds comprised of two nucleotides connected to form a ring structure. Multiple published preclinical studies have shown that STING agonists can potentiate immunotherapy efficacy when used in combination with immune checkpoint inhibitors, indicating the potential of STING agonists as a novel immunotherapy strategy.

For details regarding the incidence of solid tumors in China, see “– Our Pipeline – Oncology Franchise – Other Modalities (Immunotherapies and Targeted Therapies) – SKB337.” As of the Latest Practicable Date, according to Frost & Sullivan, there were no STING agonists approved worldwide. Including A296, there were four STING agonists in phase 1 or beyond in China as of the Latest Practicable Date, all of which were in phase 1. The first-generation STING agonists that entered clinical stage are in the form of CDNs, which are unstable and thus require intratumoral injection that severely limit their clinical applicability.

To address this shortcoming, we designed A296 with a novel non-CDN hybrid bimolecular structure to improve drug activity, stability and solubility. These improved properties of A296 potentially lead to durable STING activation and allow effective drug administration via IV and intratumoral routes, thus potentially increasing applicability.

We received IND approvals from the NMPA in January and June 2022 separately for a phase 1a trial (administration via IV infusion) and a phase 1 trial (administration via intratumoral injection) to evaluate A296 for IV injection and intratumoral injection, respectively, in advanced solid tumor patients. We initiated the phase 1a trial and the phase 1 trial in April and July 2022, respectively both in China. We expect to complete the phase 1a trial in the first half of 2025 and the phase 1 trial in the first half of 2026.

A296 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

BUSINESS

Non-Oncology Franchise

A223 – A JAK1/2 Inhibitor

Overview

A223 is potentially one of the first domestically developed small molecule JAK1/2 inhibitors for multiple autoimmune diseases with large patient populations in China, such as RA and AA. RA is a prevalent autoimmune disease that requires long-term treatment. Inhibiting JAKs is a clinically validated approach for treating RA, with three JAK inhibitors, each with a different selectivity to the four JAKs, approved by the NMPA in China for treating RA. Among them, JAK1/2 inhibitor Olumiant has been demonstrated to better improve the symptoms of RA patients based on cross-trial comparisons of clinical trials of the combination treatment with methotrexate (MTX) for treating RA. However, the approved JAK inhibitors have major safety issues, with black box warning issued by the FDA for increased risks of serious side effects including serious infection, death, malignancy, thrombosis, and major adverse cardiovascular events. Configured with a structural design that retains target selectivity with optimized pharmacological properties, A223 has demonstrated an encouraging safety profile in three completed trials and two ongoing trials, where most TEAEs were mild or moderate with no incidence of black box warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated promising anti-rheumatic efficacy in moderate-to-severe RA patients, with A223 2 mg achieving substantial and statistically significant ACR20 difference of 35.1% (63.6% vs. 28.6%) and ACR50 difference of 33.7% (39.4% vs. 5.7%) at week 12 compared with placebo. Notably, based on non-head-to-head comparison, the ACR20 and ACR50 differences achieved by A223 2 mg are greater than those of Olumiant 4 mg, the approved dosage of Olumiant in China, in Chinese patients with moderate-to-severe RA (ACR20 difference vs. placebo: 30.8%; ACR50 difference vs. placebo: 20.7%). These promising clinical results indicates the potential of A223 to be an effective treatment option with improved efficacy and safety for RA.

Based on the promising preliminary results from A223's ongoing phase 2 trial, we plan to commence a pivotal phase 3 trial in patients with moderate-to-severe RA in China in the second half of 2023. We have also expanded A223's target indication to AA, a common autoimmune disease of the hair follicle, with Olumiant being the first and only systemic treatment approved by the FDA for severe AA and one of the only two disease-specific treatments for the same indication approved in China as of the Latest Practicable Date. We initiated a phase 2 trial for severe AA in China in August 2022, for which we expect to complete patient enrollment in the second half of 2023.

Mechanism of Action

A223 is a small molecule that selectively inhibits two major types of JAKs, JAK1 and JAK2. The JAK-signal transducers and activators of transcription (STAT) pathway is a key signaling route through which cytokines transduce extracellular signals to induce inflammation, control immune response, and orchestrate hematopoiesis, the process through which our body manufactures blood cells. JAKs are a group of four enzymes associated with cytokine receptors and become activated upon cytokine exposure. Via their enzymatic activities, activated JAKs recruit and activate downstream signaling molecules STATs, which drive cytokine-responsive gene expression programs in the nucleus.

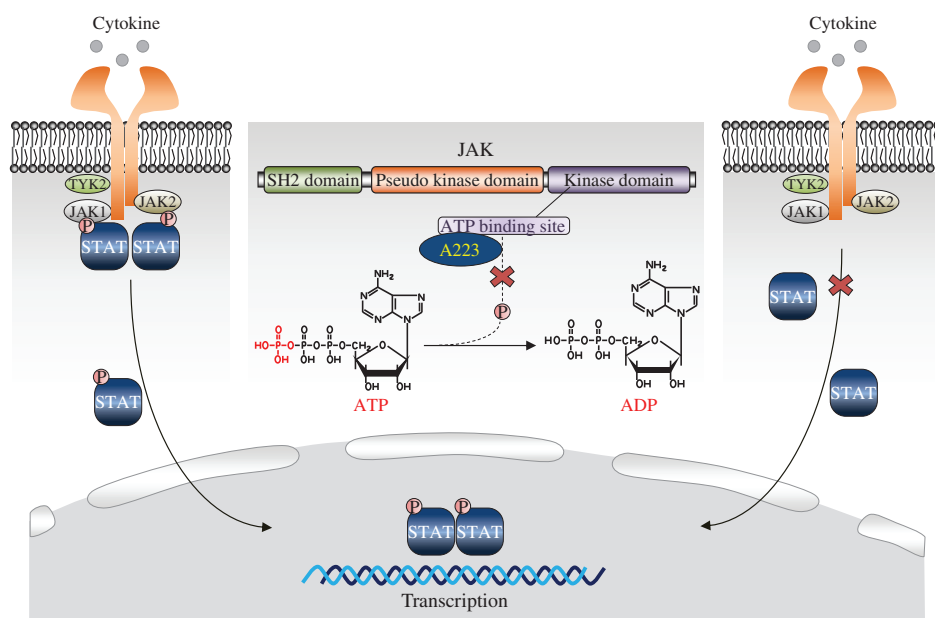
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RA is a chronic autoimmune disease characterized by systemic inflammation and subsequent progressive destruction of joints. Continuous activation of the JAK-STAT pathway by proinflammatory cytokines leads to the abnormal stimulation of the innate and adaptive immune system, causing persistent joint inflammation that damages joint tissues.

AA is a T cell-mediated autoimmune disease of the hair follicle that ranges in presentation from circular patches on the scalp to complete hair loss. Although the etiology of AA is not completely understood, the pathogenesis of AA is associated with the overexpression of proinflammatory cytokines that signal through the JAK/STAT pathway. This consequently causes cytotoxic T cells to attack hair follicles, resulting in hair loss.

Because of their critical role in mediating the signals from multiple cytokines involved in the pathogenesis of many immune-mediated disorders, JAKs have become attractive targets for treating diverse autoimmune diseases such as RA and AA.

Mechanistically, A223 competes with adenosine triphosphate (ATP) for the ATP-binding site of JAK1/2. Since the enzymatic activity of JAK1/2 requires ATP, the binding of A223 inhibits the activity of JAK1/2. This interrupts JAK-STAT signaling, thereby suppressing cytokine-mediated inflammation and preventing the progression of joint damage in RA and hair follicle damage in AA. The diagram below illustrates the mechanism of action of A223.



Market Opportunity and Competition

RA. RA is a prevalent chronic systemic autoimmune disease in which joints are inflamed, resulting in swelling and pain. As the disease progresses, gradual bone erosion and joint destruction may occur, significantly compromising the quality of life of patients. According to Frost & Sullivan, the prevalence of RA in China increased from 5.8 million in 2017 to 6.0 million in 2022 and are forecasted to reach 6.2 million in 2030.

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There is currently no cure for RA. The management of RA in China aims to achieve low disease activity or remission and to control joint damage and pain via the long-term use of disease-modifying anti-rheumatic drugs (DMARDs).

Compared to biologic DMARDs (bDMARDs) that target individual cytokines, JAK inhibitors can simultaneously interrupt the downstream signaling of multiple cytokines, which potentially underlies their effectiveness in RA patients who have failed multiple csDMARDs/bDMARDs therapies. Moreover, bDMARDs are large proteins that may cause immunogenicity, i.e., evoking an undesirable immune response, and require either intravenous infusion or subcutaneous injection for dosing. Conversely, JAK inhibitors are small molecules that are non-immunogenic and can be administered orally, thus potentially improving ease of dosing and treatment compliance.

According to Frost & Sullivan, as of the Latest Practicable Date, there were three JAK inhibitors (Xeljanz (tofacitinib), Olumiant (baricitinib) and Rinvoq (upadacitinib)), each with a different selectivity to the four JAKs, approved by the NMPA in China for treating RA. Among them, JAK1/2 inhibitor Olumiant has been demonstrated to better improve the symptoms of RA patients based on cross-trial comparisons of clinical trials of the combination treatment with methotrexate (MTX) for treating RA. In a head-to-head clinical trial for RA, Olumiant was also found to be more efficacious than Xeljanz with a comparable safety profile. These suggest Olumiant may have a better therapeutic potential than JAK inhibitors with other JAK specificities. However, the approved JAK inhibitors have major safety issues, with black box warning issued by the FDA for increased risks of serious side effects including serious infection, death, malignancy, thrombosis, and major adverse cardiovascular events. This underscores a significant unmet need for novel JAK inhibitors with improved safety profile. As of the Latest Practicable Date, according to Frost & Sullivan, there were seven JAK inhibitors in phase 2 or beyond in China for RA. For further details, see “Industry Overview – China’s JAK Inhibitor Market – Competitive Landscape of JAK Inhibitors.”

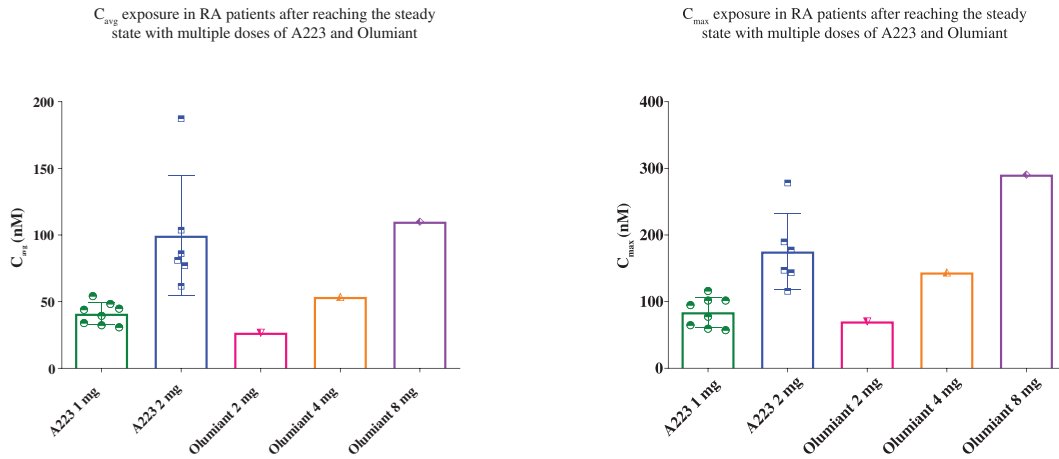
AA. AA is a common, distressing autoimmune disease in which immune cells in the body attack hair follicles, causing hair loss. According to Frost & Sullivan, the prevalence of AA in China rose from 3.5 million in 2017 to 4.0 million in 2022 and is projected to rise to 4.5 million in 2030.

Currently, treatment options for AA are limited in China with only Minoxidil, a potassium channel opener, and Olumiant approved as the only disease-specific treatments for severe AA. Inhibiting JAK1/2 represents a clinically proven strategy for AA, underlined by the FDA approval of Olumiant as the first and only systemic treatment for severe AA and its recent NMPA approval for the same indication. As of the Latest Practicable Date, according to Frost & Sullivan, there were four JAK inhibitors in phase 2 or beyond in China for AA. For further details, see “Industry Overview – China’s JAK Inhibitor Market – Competitive Landscape of JAK Inhibitors.”

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Competitive Advantages

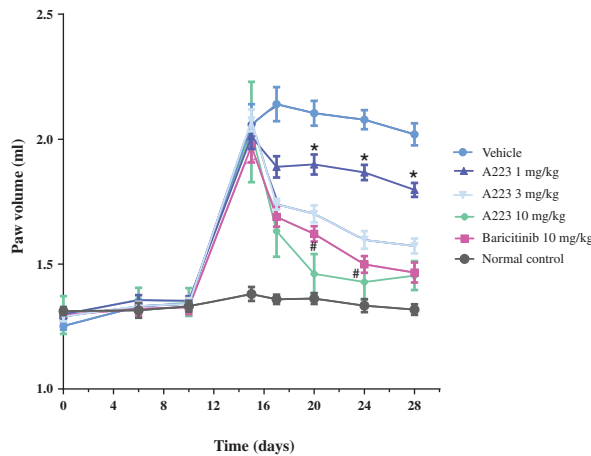
Potentially Lower Effective Dose. A223 is configured with a structural design that retains target selectivity with optimized pharmacological properties. In its phase 1b trial in RA patients, A223 at 2 mg demonstrated a comparable level of C_{avg} compared with Olumiant at 8 mg, while the C_{max} of A223 at 2 mg was significantly lower than that of baricitinib at 8 mg, based on non-head-to-head cross-trial comparison as shown in the diagram below.



Sources:

Olumiant: Olumiant’s FDA filing documents.

Moreover, in a head-to-head collagen-induced arthritis (CIA) rat model, a widely used *in vivo* model to mimic joint inflammatory symptoms in RA, CIA rat treated with A223 at 3 mg/kg showed a comparable reduction of paw swelling (an indicator of RA joint inflammation) to that of Olumiant (baricitinib) at 10 mg/kg, while those treated with A223 at 10 mg/kg had a greater paw swelling reduction than baricitinib at the same dose, as shown in the diagram below. This, together with the PK results from A223’s phase 1b trial, suggests that A223 may be effective at a lower dose than Olumiant with potentially reduced side effects.



*: A223 1 mg/kg compared with Vehicle, $p < 0.01$
 #: A223 10 mg/kg compared with baricitinib, $p < 0.05$

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Promising Anti-rheumatic Efficacy. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated dose-dependent ACR20 responses in moderate-to-severe RA patients. A223 1 mg and 2 mg achieved substantial and statistically significant ACR20 differences of 31.4% (60.0% vs. 28.6%) and 35.1% (63.6% vs. 28.6%), respectively, at week 12 compared with placebo. Moreover, A223 2 mg also achieved substantial and statistically significant ACR50 differences of 33.7% (39.4% vs. 5.7%), at week 12 compared with placebo.

Notably, as shown in the table below, the ACR20 and ACR50 differences (vs. placebo) achieved by A223 2 mg are greater than those of Olumiant 4 mg, the approved dosage of Olumiant in China, in Chinese patients with moderate-to-severe RA (ACR20 difference vs. placebo: 30.8%; ACR50 difference vs. placebo: 20.7%), based on non-head-to-head cross-trial comparison. These promising clinical results indicates the potential of A223 to be an effective treatment option with improved efficacy and safety for RA.

Non-head-to-head comparison of ACR20 and ACR50 differences (treatment vs. placebo) of A223 and Olumiant

	ACR20 difference			ACR50 difference		
	Treatment ACR20 (%)	Placebo ACR20 (%)	(treatment vs. placebo) (%)	Treatment ACR50 (%)	Placebo ACR50 (%)	(treatment vs. placebo) (%)
A223 1mg	60.0	28.6	31.4	20.0	5.7	14.3
A223 2mg	63.6	28.6	35.1	39.4	5.7	33.7
Olumiant 4mg	53.4	22.6	30.8	25.0	4.3	20.7

Sources: *Olumiant: Yang Y, et al. Rheumatol Ther 2020*

Encouraging Safety Profile. In line with our PK results, A223 demonstrated encouraging safety profile across three completed trials and two ongoing trials, where most TEAEs were mild or moderate with no incidence of black box warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary data from A223’s phase 2 trial in moderate-to-severe RA patients, the overall incidence of TEAEs across the A223 treatment cohorts (52.5%) was comparable to that of the placebo cohort (58.5%), with no obvious dose-dependent incidence of TEAEs in the treatment cohorts. Altogether, these results indicate the encouraging safety profile of A223.

Clinical Development Plan

We are rapidly progressing the clinical development of A223 in China. Based on the promising preliminary results from our ongoing phase 2 trial, we plan to initiate a pivotal phase 3 trial of A223 in moderate-to-severe RA patients in China in the second half of 2023. We have also expanded A223’s target indication to AA, with a phase 2 trial initiated in August 2022 in China for severe AA. We expect to complete patient enrollment of this trial in the second half of 2023.

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The table below sets forth our clinical development plan for A223:

Indication	Trial phase	Trial status	(Expected) Trial start date	Expected trial end date	Location
Moderate-to-severe RA	Phase 3	CDE clinical consultation	(2H 2023)	2H 2025	China
Severe AA	Phase 2	Ongoing	August 2022	2H 2024	China

Summary of Clinical Trial Data

We initiated a phase 1 clinical trial in healthy subjects in China in October 2018 and completed this trial in March 2020. We also initiated two phase 1b trials in RA patients in China in October 2019 and June 2021, and completed these two trials in June 2022 and July 2022, respectively. We initiated an ongoing phase 2 trial in December 2020 to evaluate the safety and efficacy of A223 in patients with moderate-to-severe RA. For severe AA, we received IND approval in March 2022 and initiated a phase 2 clinical trial in China in August 2022. Set forth below is a summary of the key data from A223's completed and ongoing clinical trials.

Phase 2 Clinical Trial for Moderate-to-severe RA

This is a multi-center, double-blind, randomized, placebo-controlled trial to evaluate the safety and efficacy of A223 versus MTX in patients with moderate-to-severe RA. This trial plans to enroll 160 subjects across 31 clinical research centers in China.

Trial Objectives. The primary endpoint is the American College of Rheumatology (ACR)20 response rate, which is a well-established standard that measures twenty percent improvement in patients' RA symptoms. The secondary endpoints are the proportion of patients who achieved ACR50/70, the proportion of patients who achieved remission or low disease activity, change of patients' health status.

Trial Progress. As of the Latest Practicable Date, this trial was ongoing with patient enrollment completed in November 2022. 160 patients were randomized into 0.5 mg (N=40), 1 mg (N=40), 2 mg (N=39) dose cohorts to receive the corresponding dose of A223 once daily and MTX once weekly, or the placebo cohort (N=41) to receive MTX tablet once weekly.

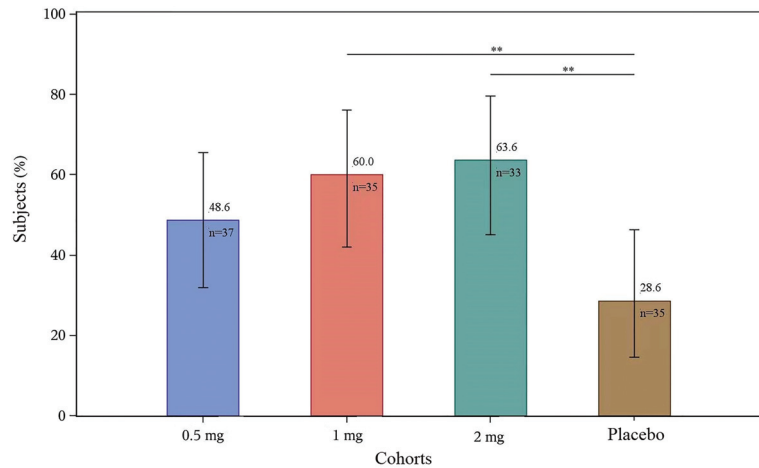
Trial Design. The trial consists of two parts. In part A, subjects were randomized 1:1:1:1 to receive MTX tablet once weekly plus 0, 0.5, 1, or 2 mg of A223 oral capsule once daily for 12 consecutive weeks. In part B, which begun after the completion of part A, subjects who received 0 mg of A223 oral capsule are randomized 1:1 into A223 0.5 mg and 1 mg cohorts, and those who received 0.5, 1, and 2 mg of A223 continue to receive the same dose once daily for 12 consecutive weeks.

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Based on preliminary data as of the data cut-off date (December 27, 2022), A223 demonstrated a dose-dependent ACR20 response (primary endpoint) in moderate-to-severe RA patients, with an ACR20 response of 48.6%, 60.0% and 63.6% in the 0.5 mg, 1 mg and 2 mg A223 dose cohorts. In particular, the ACR20 responses of the 1 mg and 2 mg A223 cohorts were substantially and statistically significantly higher than that of the placebo cohort (28.6%), as illustrated in the diagram and bar chart below.

	A223 0.5 mg	A223 1 mg	A223 2 mg	Placebo
Patient number	37	35	33	35
ACR20 (%)	48.6	60.0	63.6	28.6
ACR20 difference between treatment cohort and placebo cohort (%)	20.1	31.4	35.1	
P-value	0.081	0.008	0.004	

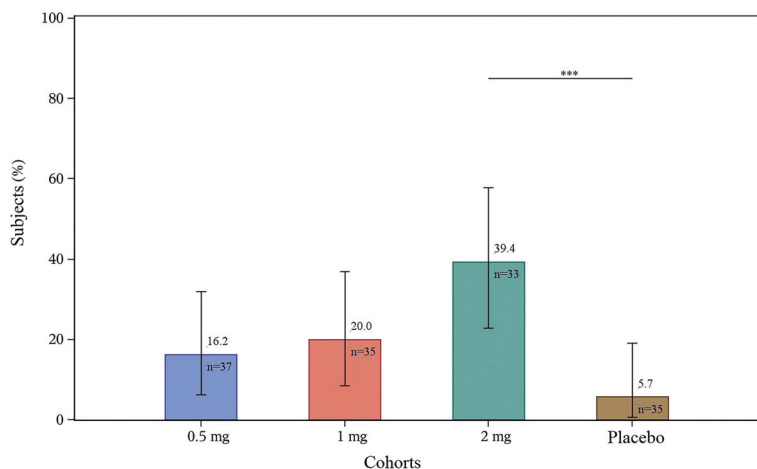
ACR20 responses of A223 vs. placebo in moderate-to-severe RA patients



Further, A223 demonstrated a dose-dependent ACR50 response (secondary endpoint), with a substantially and significantly higher (p-value < 0.05) ACR50 difference between the 2 mg A223 cohort and the placebo cohort, as shown in the bar chart below. Moreover, compared with the placebo cohort, other secondary endpoints, including DAS28-ESR<2.6, DAS28-CRP≤3.2, DAS28-ESR≤3.2 and HAQ-DI score, in the 2mg A223 cohort at week 12 were significantly improved (p-value < 0.05).

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ACR50 responses of A223 vs. placebo in moderate-to-severe RA patients



Safety Data. Based on preliminary data as of the data cut-off date (December 27, 2022), A223 was generally safe and well-tolerated. The overall incidence of TEAEs across the A223 treatment cohorts (52.5%) was comparable to that of the placebo cohort (58.5%) and there was no obvious dose-dependent incidence of TEAEs in the treatment cohorts. One patient (2.5%) with grade three or above TEAE occurred in each of the 0.5 mg and 1 mg A223 cohorts, and two patients (4.9%) with grade three or above TEAE occurred in the placebo group. All other TEAEs were mild or moderate (grade ≤ 2), with the majority of them being grade 1. The following table summarizes the incidence of TEAEs as of the data cut-off date.

	A223 0.5mg (N=40) n (%)	A223 1mg (N=40) n (%)	A223 2mg (N=38) n (%)	A223 treatment cohorts total (N=118) n (%)	Placebo cohort (N=41) n (%)
Any TEAE	19 (47.5)	24 (60.0)	19 (50.0)	62 (52.5)	24 (58.5)
Study drug-related TEAE¹	10 (25.0)	13 (32.5)	13 (34.2)	36 (30.5)	10 (24.4)
≥ Grade 3 TEAE	1 (2.5)	1 (2.5)	0	2 (1.7)	2 (4.9)
TEAE that led to death	0	0	0	0	0

Note:

(1) As of the data cut-off date (December 27, 2022), there were 159 patients who received at least one dose of A223 or placebo and were evaluable for safety assessment.

Conclusion. Based on preliminary data, A223 demonstrated promising anti-rheumatic efficacy, indicated by substantially and statistically significantly higher ACR20 responses at 1 and 2 mg as well as ACR50 response at 2 mg compared to placebo. A223 also exhibited a good safety profile with most TEAEs being mild or moderate.

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Phase 2 Clinical Trial for Severe AA

This is a multi-center, double-blind, randomized, placebo-controlled trial to evaluate the safety and efficacy of A223 in patients with severe AA. The trial plans to enroll 176 adults (≥ 18 years and ≤ 65 years), who have 50% or greater scalp-hair loss, in 29 clinical research centers in China.

Trial Objectives. The primary endpoint is the proportion of patients with the Severity of Alopecia Tool (SALT, a method to assess the extent of scalp-hair loss in AA patients) score ≤ 20 by week 24. The secondary endpoints include the proportion of patients with SALT score ≤ 20 by week 36, SALT score ≤ 10 by week 24 and 36, 50% and 75% improvement of SALT relative to baseline by week 24 and 36, as well as changes of SALT relative to baseline by week 24 and 36 and the exposure-response relationship of A223 in patients with severe AA.

Trial Progress. As of the Latest Practicable Date, patient enrollment of this trial was ongoing, with first-patient-in achieved in November 2022.

Trial Design. Subjects are randomized 1:1:1:1 into either the treatment cohorts to receive 0.5, 1 or 2 mg of A223 oral capsule once daily for 36 consecutive weeks, or the placebo cohort.

Phase 1b Drug-drug Interaction Clinical Trial with MTX for Moderate-to-severe RA

This was a multi-center, double-blind, randomized trial to evaluate the PK and safety profile of A223 in combination with MTX in patients with moderate-to-severe RA. This trial was conducted in 31 subjects across eight clinical research centers in China.

Trial Objectives. The primary endpoints were the PK profiles of A223, MTX, and their metabolites 7-OH. The secondary endpoint was the safety of A223 and MTX.

Trial Progress. This trial was completed in July 2022.

Trial Design. All subjects received a single dose of 10 mg of MTX oral tablet on day 1 and day 8 and a single dose of 2 mg of A223 oral capsule once daily from day 3 to day 14.

Safety Data. The combination treatment of MTX and A223 was generally safe and well-tolerated. There was no incidence of TEAEs that led to temporary treatment withdrawal, treatment discontinuation and death. Most TEAEs were mild or moderate (grade ≤ 2) and reversible without additional medical intervention, with the most common ones being elevated level of blood lipids and abnormal blood cell count. One SAE was reported and it was considered by the trial investigator to be possibly unrelated to the study drug.

PK Data. PK analysis in 31 patients showed that the combination treatment of MTX and A223 did not affect major PK parameters including C_{max} , time to peak drug concentration and AUC.

Conclusion. Combination treatment of A223 with MTX exhibited good drug compatibility based on the safety and PK data, supporting the potential of A223 as part of MTX combination therapy with low risks of serious side effects and undesirable PK behaviors.

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Phase 1b Clinical Trial for RA

This was a double-blind, randomized, placebo-controlled trial to evaluate the safety, tolerability, PK/PD of A223 and to explore the safe and effective dose range of A223 in patients with RA to provide the basis for the dosing regimen of A223 in subsequent phase 2 trials. The trial was conducted in 30 subjects in one clinical research center in China.

Trial Objectives. The primary endpoint was the safety of A223. The secondary endpoints were the PK/PD profile of A223, ACR20/50/70 response rates, the proportion of patients who achieved remission or LDA and health status of RA patients.

Trial Progress. This trial was completed in June 2022.

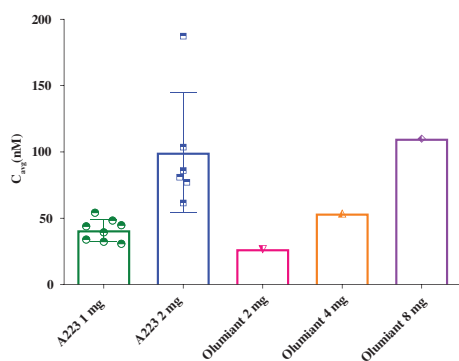
Trial Design. Subjects were randomized to receive a single dose of either 1, 2, or 4 mg of A223 oral capsule or placebo. After completing a single dose and a subsequent 7-day washout period, subjects continued to receive the same dose once daily for 14 days.

Efficacy Data. A223 demonstrated potential efficacy in patients with moderate-to-severe RA after two weeks of treatment. A223 treatment at 2 mg showed the highest efficacy as measured by ACR20 response rate (37.5%), while ACR20 response rate in the placebo cohort was 16.7%.

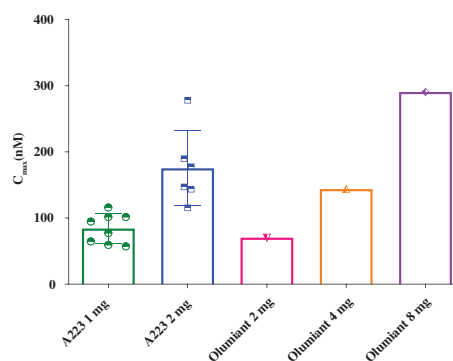
Safety Data. A223 were generally safe and well-tolerated. All AEs were mild or moderate (grade ≤ 2) and were reversible without additional medical intervention. The most common AEs were abnormal blood lipids and abnormal blood cell count.

PK Data. PK in RA patients showed similar trends to those in healthy individuals. As shown in the diagrams below, in non-head-to-head cross-trial comparison with Olumiant, A223 demonstrated significantly lower levels of C_{max} than Olumiant at comparable levels of C_{avg} . This suggested that A223 may have a lower minimum effective dose than Olumiant and thus may be potentially safer and better tolerated while maintaining comparable efficacy as Olumiant.

C_{avg} exposure in RA patients after reaching the steady state with multiple doses of A223 and Olumiant



C_{max} exposure in RA patients after reaching the steady state with multiple doses of A223 and Olumiant



Sources: Olumiant: Olumiant's FDA filing documents

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Conclusion. A223 demonstrated potential efficacy in moderate-to-severe patients with a good safety profile and PK properties consistent with those observed in healthy individuals. Based on PK analysis results, A223 may have a lower minimum effective dose than Olumiant, suggesting that it may be potentially safer and better tolerated while maintaining comparable efficacy as Olumiant.

Phase 1 Clinical Trial in Healthy Subjects

This was a double-blind, randomized, placebo-controlled trial to evaluate the safety, tolerability, PK/PD activity, dosing schedule and the effect of A223 on QTcF interval, an electrocardiogram measurement of cardiac electrical properties, in healthy Chinese subjects. The trial was conducted in 79 subjects in one clinical research center in China.

Trial Objectives. The primary endpoint was the safety of A223. The secondary endpoints were the PK/PD profile and QTcF interval parameters of A223.

Trial Progress. This trial was completed in August 2019.

Trial Design. The trial consisted of single-dose and multi-dose phases. In the single-dose phase, subjects were randomized to receive 1, 2, 4, 6, 8, 10, 15, or 20 mg of A223 oral capsule or placebo. Subjects who completed a single dose of 2, 4 and 6 mg of A223 oral capsule underwent a 120-hour washout period with safety/tolerability assessment. Subjects who completed the washout period with no reported safety issues would be selected for the multi-dose phase. The subject’s dose level in the multi-dose phase was the randomized dose (2, 4, or 6 mg) administered in the single dose phase, with subjects receiving A223 capsule once daily for seven consecutive days.

Safety Data. A223 was generally safe and well-tolerated. There was no reported incidence of SAEs, AEs of grade 3 or above, or AEs that led to premature treatment withdrawal. All reported TEAEs were mild or moderate (grade ≤ 2), with the majority of them hematologically related, including decreased percentages/counts of neutrophils, lymphocytes, white blood cells and red blood cells in the blood. All reported TEAEs were rapidly reversible within two to three days after A223 treatment without additional medical intervention. The following table summarizes the incidence of TEAEs.

Event	A223 dose	Placebo cohort
	cohorts (N=62)	(N=16)
	Total (n, %)	Total (n, %)
Any TEAE	55 (88.7)	13 (81.3)
Drug-related TEAE ⁽¹⁾	54 (87.1)	13 (81.3)
TEAE grade 1 ⁽²⁾	38 (61.3)	11 (68.8)
TEAE grade 2 ⁽²⁾	17 (27.4)	2 (12.5)
TEAE grade 3 or above ⁽²⁾	0	0

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Notes:

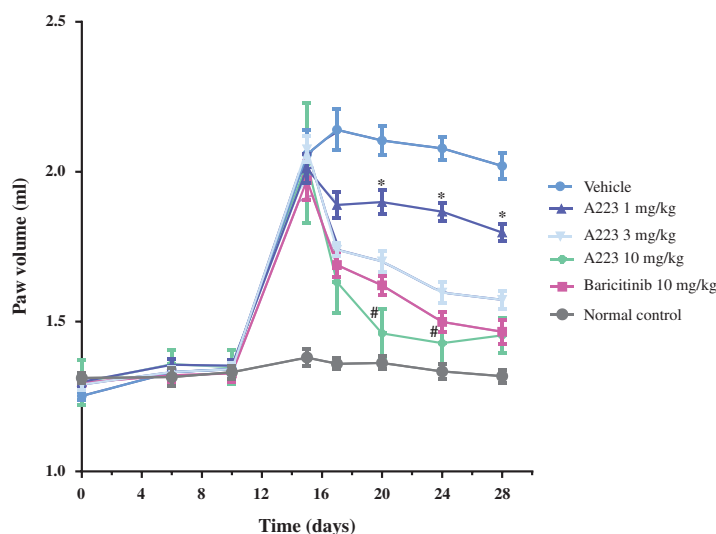
- (1) Drug-related TEAEs refer to events classified as related, probably related, or possibly related to the study medication.
- (2) TEAE severity was calculated and graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (standard version 5.0).

PK Data. After single-dose administration, A223 demonstrated a half-life between 14.02 to 17.76 hours (h), average oral clearance between 2.75 to 3.50 L/h and average apparent volume of distribution during terminal phase (V_z/F) between 61.53 to 78.30 L. After multiple-dose administration, A223 demonstrated a half-life between 15.79 to 17.89 h, average CL/F between 2.45 to 3.11 L/h and average V_z/F between 60.79 to 76.31 L.

Conclusion. A223 exhibited a good safety profile in healthy participants with desirable PK properties.

Summary of Preclinical Data

We studied A223 and Olumiant (baricitinib) head-to-head in a (CIA) rat model, which is a widely used *in vivo* model to mimic joint inflammatory symptoms in RA. As shown in the diagram below, the onset of arthritis appeared on about Day 10 with peak onset on about Day 14, as indicated by significantly more paw swelling (expressed as an increase in paw volume) compared to normal control. Daily treatment of A223 at 1, 3 and 10 mg/kg and baricitinib at 10 mg/kg substantially reduced paw swelling, indicated by the reduced paw volume following drug administration on Day 15 compared to vehicle. Notably, CIA rat treated with A223 at 3 mg/kg showed paw swelling reduction comparable to that of baricitinib at 10 mg/kg, while those treated with A223 at 10 mg/kg had a greater paw swelling reduction than baricitinib at the same dose, indicating that A223 may have a lower effective dose than baricitinib.



Notes:

- *: A223 1 mg/kg compared with vehicle, p-value < 0.01
- #: A223 10 mg/kg compared with baricitinib, p-value < 0.05

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Next Steps

Based on the preliminary results from A223’s phase 2 trial in moderate-to-severe RA patients, we are consulting the CDE regarding the design of a pivotal phase 3 trial. We expect to initiate the pivotal phase 3 trial in the second half of 2023. For severe AA, we expect to complete patient enrollment of our ongoing phase 2 trial in the second half of 2023.

A223 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A277 – A Peripherally-restricted KOR Agonist

A277 is potentially one of the first peripherally-restricted KOR agonists for treating CKD-aP in China, a distressing chronic itching condition with large and underserved patient population. As of the Latest Practicable Date, there were no approved treatments specifically targeting CKD-aP in China. KOR agonists have been shown to inhibit pruritus, by counteracting the pro-itching effects of mu opioid receptors (MORs), in both animals and humans. Selectively activating peripheral KORs thus represents a promising therapeutic approach for treating CKD-aP, supported by the recent FDA approval of Korsuva as the first and only peripherally-restricted KOR agonist to date for treating moderate-to-severe CKD-aP.

CKD-aP is a common condition of intense and systemic itchy skin for patients with CKD. It is more prevalent in patients on hemodialysis and those with advanced CKD, affecting over 60% of hemodialysis patients and 40% of ESRD patients. According to Frost & Sullivan, the prevalence of CKD increased from 120.4 million in 2017 to 140.8 million in 2022 and is projected to reach 171.9 million in 2030. According to the same source, there were five peripherally-restricted KOR agonists candidates in phase 1 or beyond in China for CKD-aP as of the Latest Practicable Date.

A277 is a novel peripherally-restricted KOR agonist that selectively activates KORs, but not mu opioid receptors (MORs) or other opioid receptors. A277 is specifically designed to restrict its entry into the CNS and limit its action selectively to KORs on sensory nerves outside the brain and on certain immune cells, thereby potentially minimizing opioid-induced drug dependence, respiratory depression and constipation, as well as dysphoria and hallucination associated with centrally-acting KOR agonists. A277 demonstrated potential efficacy and good safety in a completed phase 1b clinical trial, where it exhibited potential in reducing the pruritus numerical rating scale, a widely adopted standard for evaluating itch intensity, in maintenance hemodialysis patients with moderate-to-severe CKD-aP, with no incidence of opioid-induced drug dependence, respiratory depression and constipation. These positive clinical results indicate the potential of A277 as a safe and effective therapeutic option for CKD-aP.

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We are actively progressing the clinical development of A277 in China. We initiated a phase 1 clinical trial in healthy subjects in China in November 2018 and completed this trial in January 2021. We also initiated a phase 1b trial in maintenance hemodialysis patients with moderate-to-severe pruritus in China in August 2020. Having completed this phase 1b trial in January 2022, we commenced a phase 2 trial in maintenance hemodialysis patients with moderate-to-severe pruritus in China in September 2022. We expect to complete this trial in the first half of 2024.

A277 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB378 – A TSLP mAb

SKB378 is potentially the first domestically developed TSLP mAb in China for treating patients with moderate-to-severe asthma, a prevalent chronic airway disease and a primary cause of morbidity and socioeconomic burden worldwide. The current mainstay treatment options of moderate-to-severe asthma are only effective for patients with a specific asthma inflammatory phenotype, underscoring a significant unmet need for innovative therapies applicable to a broader population of asthma patients.

SKB378 targets TSLP, an important cytokine implicated in the pathophysiology of asthma as a key orchestrator of the underlying inflammation. Asthma can be broadly classified into two clinical inflammatory phenotypes, eosinophilic and noneosinophilic, which are respectively characterized by type 2 and non-type 2 inflammation with distinct immune response patterns. Given the major role of TSLP in both types of asthma based on recent published studies, targeting TSLP represents a promising strategy for treating asthma without phenotypic limitations. According to Frost & Sullivan, the prevalence of moderate-to-severe asthma in China rose from 21.5 million in 2017 to 23.6 million in 2022. This number is expected to reach 27.4 million in 2030.

Currently, the approved treatment options of moderate-to-severe asthma in China are mAbs that target type 2 inflammatory pathways and are thus ineffective for patients with noneosinophilic asthma, which account for approximately 50% of moderate-to-severe asthma cases. Tezepelumab, a TSLP mAb that achieved effective asthma control and exacerbation reduction regardless of patients’ (non)eosinophilic phenotypes, is the only anti-TSLP treatment approved in the U.S. for severe asthma. As of the Latest Practicable Date, there were nine anti-TSLP therapies in phase 1 or beyond in China.

We received IND approval from the NMPA in February 2022 and initiated a phase 1 clinical trial in healthy subjects in August 2022 in China, which we expect to complete in the second half of 2023.

SKB378 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

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SKB336 – A FXI/FXIa mAb

SKB336 is a novel FXI/FXIa mAb designed as an anticoagulant for preventing and treating thromboembolic disorders, starting with venous thromboembolism (VTE) after total knee arthroplasty (TKA). Thromboembolic disorders are prevalent and potentially fatal conditions in which abnormally formed blood clots block blood vessels. The current mainstay anticoagulant therapies put patients at increased risks of severe and potentially life-threatening bleeding complications as their targets are also required for normal coagulation, leaving a substantial unmet need for novel effective anticoagulation agents with limited risk of bleeding.

FXI/FXIa have emerged as a promising anticoagulation target as these factors are not essential for initiating normal blood coagulation, but play a central role in promoting thrombosis, which refers to abnormal coagulation that leads to blood clots developing in a blood vessel. In published preclinical studies, FXI/FXIa deficiencies led to clot instability and prevented the occlusion of blood vessels, suggesting that targeting FXI/FXIa is potentially a safe and effective strategy for preventing and treating thromboembolic disorders, such as VTE after TKA.

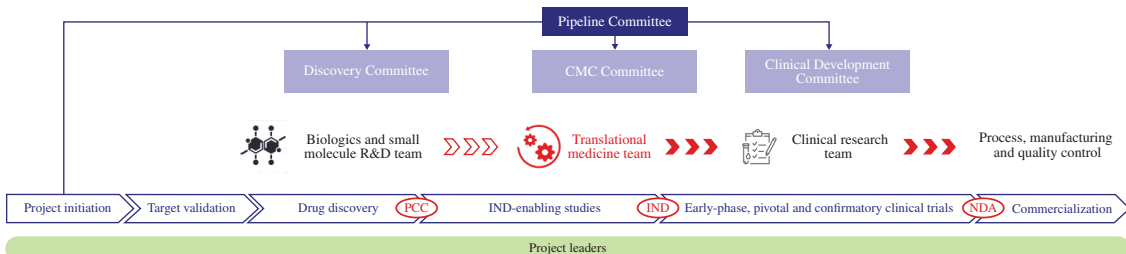
According to Frost & Sullivan, VTE is the third leading vascular diagnosis after heart attack and stroke in China, affecting approximately 3.2 million people in 2022. VTE is commonly triggered by cancer, immobilization, hospitalization and surgery, such as TKA, a common procedure for treating end-stage osteoarthritis. According to the same source, the number of TKA in China grew from 240.1 thousand in 2017 to 360.8 thousand in 2022 at a CAGR of 8.5%, and is projected to rise to 2.9 million in 2030 at a CAGR of 29.8%. As of the Latest Practicable Date, there were no anti-FXI/FXIa drugs approved by the NMPA and two anti-FXI/FXIa drugs were in phase 1 or beyond in China. According to Frost & Sullivan, SKB336 is the first domestically developed anti-FXI/FXIa drug to enter clinical stage in China.

We received IND approval from the NMPA in July 2021 for preventing and treating thromboembolic disorders. We initiated a phase 1a clinical trial in healthy subjects in July 2021 and completed this trial in November 2022.

SKB336 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

INTEGRATED DRUG DEVELOPMENT CAPABILITIES

We have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization, illustrated by the diagram below.



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Our drug development capabilities are governed by a well-established management system that covers all key business functionalities, which provides a framework for our internal teams to engage in constructive dialogue and evaluation, particularly when making critical decisions for each drug development plan. Meanwhile, we implement a dynamic global business development strategy to maximize the commercial value of our pipeline in major international markets, leveraging our experience in forging strategic partnerships worldwide.

We operate a three-tiered decision-making model, consisting of: (i) a pipeline committee led by our CEO that oversees the entire lifecycle of drug development programs, (ii) discovery, CMC, and clinical development committees that serve as gatekeepers for the progress and quality of our drug development programs, and provide timely feedback in each round of planning, and (iii) project leaders that are instrumental to the effective coordination among different functional groups to ensure smooth execution of our drug development plans.

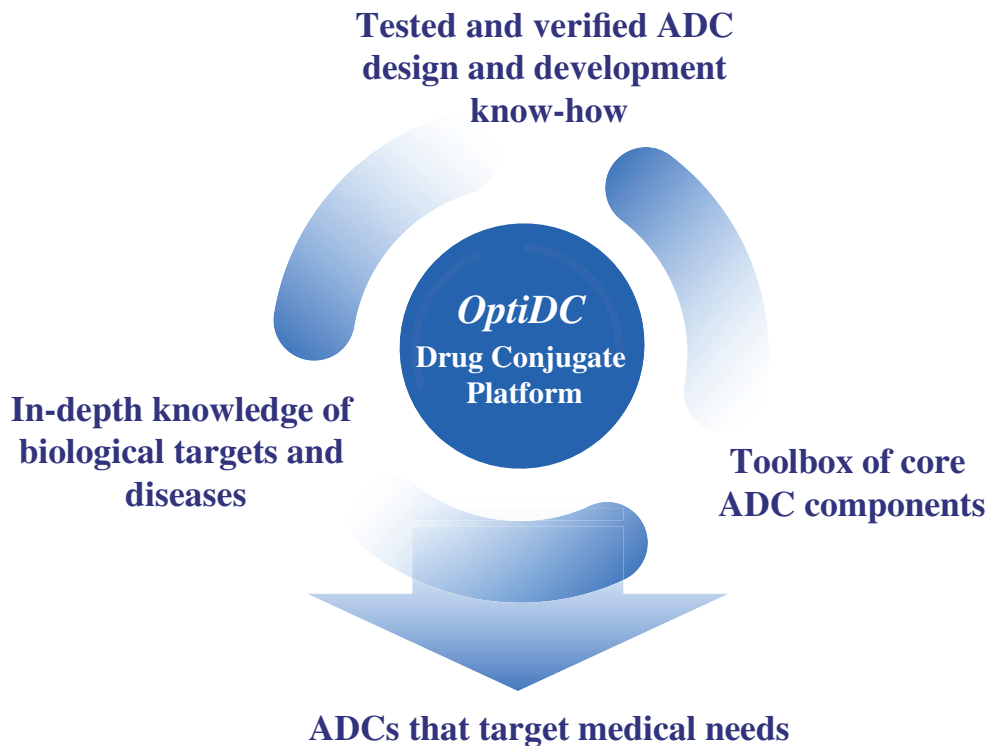
OUR TECHNOLOGY PLATFORMS

We have established three core platforms with proprietary know-how in ADC, biologics and small molecule technologies that serve as the foundation of our discovery and development of innovative medicines for medical needs in selected disease areas, such as oncology, autoimmune diseases and metabolic diseases. These platforms cover the entire R&D process for different drug modalities and are integrated to allow cross-functional synergies at crucial stages of drug development.

ADC Platform

Our ADC platform, *OptiDC*, is supported by three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified ADC design and development know-how, and a toolbox of core ADC components. Through over a decade of development, we have developed a toolbox of core ADC components which gives us the versatility to engineer customized ADCs optimized for different biological targets to address medical needs in a broad range of indications. We have honed our expertise in ADC process development, manufacturing and quality control, which we believe is crucial in bringing our ADCs from bench to bedside. Notably, our ADC platform is tested and verified through preclinical studies and clinical trials with over 1,160 patients as of the Latest Practicable Date.

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Our ADC design strategies are exemplified by *Kthiol*, our proprietary drug-linker strategy implemented in SKB264 that features an optimized balance between safety and efficacy. *Kthiol* incorporates moderately potent payload and irreversible linker conjugation to the antibody, which reduces off-target toxicity as well as on-target off-tumor toxicity of SKB264. Meanwhile, pH sensitive cleavable moiety in the linker allows efficient release of payload once reaching the tumor to improve efficacy. For more details, see “– Our Pipeline – Oncology Franchise – ADCs – SKB264 – Drug Design and Mechanism of Action.”

Key capabilities and technologies of our ADC platform encompass all major aspects of ADC development, including the following:

Antibody discovery and optimization. We have developed a bioinformatics-aided antibody discovery workflow with a repertoire of high-throughput screening systems and a robust antibody optimization workflow that involves careful assessment of antibody candidates based on critical developability, efficacy and safety parameters. These workflows allow us to produce antibodies with better target selectivity and broader therapeutic window, as well as enabling us to select optimized combination strategies of antibody with payload-linker for our ADC candidates. For details, see “– Our Technology Platforms – Biologics Platform.”

Payload screening. We have constructed an extensive library of cytotoxic small molecules and developed a smooth workflow to screen hundreds of linker-payload combinations *in vitro/in vivo* simultaneously. This enables us to efficiently identify payload molecules with desirable cytotoxicity, bystander killing capability, plasma stability, half-life and mechanisms of action that may overcome drug resistance. Leveraging our small molecule

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platform, we have in-house developed a range of proprietary payload small molecules with various modes of action (e.g. cytotoxic killing and immune modulation) for pairing with different types of linkers, providing us with the versatility to achieve optimized payload-linker combinations tailored to target indications and molecular targets.

Linker modification. An ideal linker should (i) anchor the payload to the antibody stably in the circulation and release it selectively and efficiently in the tumor; and (ii) possess chemical moieties that increase overall hydrophobicity of ADC to avoid aggregation and fast clearance in the body before bringing efficacy. Leveraging our expertise on linker chemistry, we are able to create reasonably stable and hydrophilic linkers with selective cleavage in the tumor to reduce undesirable toxicities and improve therapeutic window.

Proprietary conjugation technologies. The way a linker-payload conjugates to an antibody influences the DAR as well as the stability and undesirable toxicities of the final ADC product. We have developed proprietary conjugation technologies that enable us to customize the DAR of our ADCs, which is instrumental for creating different combinations of payload toxicity and the amount of conjugated payload molecules to balance the anti-tumor potency and safety profile of each ADC.

In particular, our proprietary linker and conjugation technologies enable us to achieve site-specific and quantity-specific conjugation, without the need to modify the antibody, which is a commonly used industry practice for ADC conjugation. This allows us to produce ADCs with (1) stable conjugation and a lower risk of premature release of payload-linker in circulation, compared to other linker technology used by certain other ADC companies; (2) high homogeneity with a uniform pre-specified DAR, which leads to more consistent PK profiles and hence ADC activity, compared to ADCs that use conventional non-site-specific conjugation; (3) greater ease of engineering and lower cost, compared with ADCs engineered through antibody modifications.

Our ADC technology platform is seamlessly integrated with our manufacturing capabilities, enabling in-house production of antibodies (mAb and bsAb), linkers, payload/small molecules and final ADC products at lab, pilot and commercial scales. This allows us to continuously accumulate deep understanding of, and refine know-how on, the end-to-end development of various types of ADCs, which is integral to our ability to develop innovative ADCs with differentiated features and competitive edge.

We are establishing novel ADC designs to further advance our ADC portfolio via a multi-pronged strategy, including:

- further optimizing our payload/linker technologies to solidify our ADC capabilities, such as (i) our proprietary thiobridge linker, a next-generation linker design that enables site-specific and fixed-DAR conjugation of linker-payload, and (ii) linker with optimized hydrophilicity and stability to improve ADC PK properties and safety window;

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- developing bsADCs equipped with dual-targeting antibodies to deliver enhanced clinical benefits, such as (i) biparatopic antibodies that target different, non-overlapping binding sites on a single antigen to improve efficacy by promoting cellular uptake of an ADC, (ii) bsAbs that target two different antigens co-expressed on the same cancer cells to improve binding specificity toward cancer cells and reduce off-tumor toxicity, and (iii) TAA-IO bsAbs to enhance anti-tumor effect by simultaneously targeting TAA on tumor cells (to induce tumor cell death by activating cell death programs or inhibit pro-survival or proliferative signalling) and IO antigen (to eliminate checkpoint inhibition, engage immune effector cells, or promote release of cytokines that facilitate immune crosstalk and anti-tumor immunity);
- developing other novel ADC designs such as iADCs, RDCs, dual-payload ADCs. For example, we are harnessing the synergy between IO and tumor targeting via iADCs, which are a novel form of ADCs to activate anti-tumor immune response on top of conventional tumor-directed cytotoxin delivery, with promising efficacy and safety results observed in preclinical studies. Moreover, we are developing RDCs that carry radioactive isotopes to cancer cells. By manipulating a distinct mechanism of action, RDCs represent a promising strategy to overcome drug resistance associated with traditional cytotoxin-based ADCs. We are also developing linkers that allow dual-payload delivery to harness multiple mechanisms of action to enhance treatment responses; and
- developing ADCs with non-cytotoxic payloads to target non-oncology diseases. In addition to ADCs for treating cancers, we are developing ADCs configured with various novel, non-cytotoxic payload strategies for non-oncology diseases, such as ADCs with GR modulators as payloads to treat autoimmune diseases.

As a forerunner in ADC research and development, we are a lead participant in formulating China’s first set of technical guidelines and industry standards on ADC drug development, such as the “Technical Guidelines for Clinical Development of Anti-tumor ADC Drugs (Consultation Paper)” (《抗腫瘤抗體偶聯藥物臨床研發技術指導原則(徵求意見稿)》) published by the CDE in September 2022 and the “Expert Consensus on ADC Drug Quality Control and Preclinical Assessment” (《抗體偶聯藥物質量控制和臨床前評價專家共識》) released in July 2018.

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Biologics Platform

We have developed an extensive biologics technology platform capable of delivering quality and innovative mAbs and bsAbs to advance our pipeline of ADCs, immunotherapies and targeted therapies. The competitive edge of our biologics platform is underscored by its end-to-end antibody development capabilities ranging from antibody discovery and optimization, to bioprocessing, scale-up manufacturing and quality control, which has allowed us to successfully and efficiently advance multiple ADC, mAb and bsAb candidates to clinical stage. The core capabilities of our biologics platform are illustrated below:

Antibody discovery. We have built a bioinformatics-aided antibody discovery workflow to systematically modify the protein sequence of antibodies and identify those with desirable pharmacological properties and biological activities using a repertoire of high-throughput screening systems including hybridoma, phage display, single B cells and de novo sequencing.

Our antibody discovery workflow is highlighted by: (i) a highly efficient antibody discovery platform featuring optimized animal immunization and hybridoma fusion technologies, a fully human phage library with large capacity and diversity, as well as single B cell technologies and de novo antibody sequencing technologies; (ii) antibody evaluation platform equipped with high-throughput natural conformation target and endocytosis screening methods, systematic and scientific evaluation of drug efficacy *in vivo* and *in vitro* for cancer, autoimmunity, metabolism and other diseases, as well as developability assessment for early stage antibody discovery, including post-translational modifications, hydrophobicity, stability and immunogenicity; (iii) antibody engineering platform that features antibody humanization and physicochemical property modification, affinity maturation, antibody-target docking based on artificial intelligence technology, and specific bsAb design and construction; (iv) high yield antibody expression platform using in-house developed cell biology technologies, such as different vector construction and transfection methods that enable high transfection rate. Our antibody discovery workflow is optimized for the discovery of therapeutic antibodies, allowing seamless transition into development and manufacturing.

Antibody optimization. Building on our antibody discovery workflow, we have established a robust antibody optimization workflow that enables us to produce antibodies with better target selectivity and wider therapeutic window. This workflow comprises five major stages (from target research and antibody generation, to lead selection, lead optimization and preclinical enabling) and involves careful assessment of critical developability, efficacy and safety parameters. This allows us to generate antibody candidates with promising developability, efficacy and safety profiles.

Bioprocessing and scale-up manufacturing. We have a comprehensive in-house system that covers all the upstream and downstream bioprocessing steps throughout the development lifecycle of biologics candidates. It features (i) a cell culture platform with standardized process development and scale-up capacity, with flexible cell culture modes and capability of developing chemical-defined medium formulation, (ii) a well-established ADC conjugation and purification platform, and (iii) a formulation platform capable of developing various dosage forms such as high-concentration, lyophilized and pre-filled formulation, all of which contribute to the manufacturing of high-quality biologics candidates for clinical trial use.

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Small Molecule Platform

We have built an innovative small molecule platform focusing on target validation, molecule innovation and translational R&D. The competitive edge of our small molecule platform lies in the integration of medicinal chemistry and CADD technologies, which enable us to efficiently and scientifically identify optimized PCC molecules. Our integrated medicinal chemistry and CADD technologies are highlighted by molecular docking, pharmacophore modeling, virtual screening and ADMET prediction. Through computer simulation and calculation, CADD allows a more scientific and reasonable analysis of potential drug-target interactions. It also facilitates the prediction of key drug-like properties of potential drug candidates and the use of virtual screening to rapidly screen potential compounds from databases with over tens of thousands of chemical compounds.

These capabilities enable a more efficient and productive preclinical drug discovery by allowing us to focus on compound optimization in early-stage research, thus reducing the number of compounds synthesized for each project and significantly shortening the time required for delivering preclinical candidate. Since its inception in 2014, our small molecule platform has been instrumental in advancing innovative small molecule drug candidates for treating various cancers and chronic diseases, including four clinical-stage assets. We are also exploring state-of-the-art technologies such as PROTAC to navigate challenging protein targets.

RESEARCH AND DEVELOPMENT

We believe research and development is critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. Our integrated in-house R&D capabilities, built on our three technology platforms, give us control and visibility over our R&D process, reduces our reliance on CROs, and enable us to ensure the quality and efficiency of our drug development programs. For details regarding our technology platforms, please see “– Our Technology Platforms.”

We conduct our research and development activities primarily through an in-house R&D team, and engage CROs from time to time to support our preclinical research and clinical trials. For the years ended December 31, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million and RMB1,122.8 million, respectively. In particular, the costs and expenses in relation to R&D activities for our Core Products amounted to RMB205.9 million (including RMB60.5 million for SKB264 and RMB145.4 million for A166) and RMB461.6 million (including RMB323.6 million for SKB264 and RMB138.0 million for A166) for the years ended December 31, 2021 and 2022, respectively, accounting for 27.5% and 41.1% of our total costs and expenses in relation to R&D activities for the same years, respectively. Such costs and expenses mainly included clinical trial expenses, staff costs and costs of raw materials and consumables during the Track Record Period. We expect that our costs and expenses in relation to R&D activities will increase in line with the future growth of our business.

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In-house R&D

Our R&D team comprises industry veterans with extensive experience of driving drug development programs at leading biopharmaceutical companies. As of December 31, 2022, our R&D team had over 760 members, over half of whom held a master’s or higher degree (including 63 with a doctoral degree), mainly in medical science, pharmacology, biology and chemistry. When we recruit R&D team members, we primarily take into account the candidates’ academic qualifications, relevant industry experience, and whether their expertise complements and synergizes with our accumulated know-how. In particular, when selecting core R&D team members responsible for the development of ADC drug candidates, we further consider the candidates’ prior experience in ADC development, whether at academic institutions or with other biopharmaceutical companies, as well as their demonstrated contribution to the advancement of this new drug modality. We believe our established profile in ADC development has enabled us to recruit strong R&D talent in this emerging field.

We operate a highly systematic R&D structure under our three-tiered decision-making model. Our R&D strategy and direction is guided by our pipeline committee, which is led by our CEO and Executive Director, Dr. Ge Junyou. Our R&D team executes the vision and programs set by our pipeline committee, and plays a central role in the development of the Core Products and other pipeline candidates. Our R&D team is further divided into several centers based on the different types of R&D activities performed, including: a clinical research center, a biologics drug center, a small molecule drug center and a translational medicine center. The following table sets forth details of our R&D team as of December 31, 2022:

R&D Centers	Number	% of Total
Clinical research	392	51.2%
Biologics drug	108	14.1%
Small molecule drug	118	15.4%
Translational medicine	82	10.7%
Others	66	8.6%
Total	766	100.0%

Although we believe every role that we have created in our R&D system is important, we consider core R&D team members those who have made meaningful contribution to the discovery and development of the Core Products. These core R&D team members bring with them extensive experience driving drug discovery and development programs at leading MNCs, including Wyeth, LLC (now Pfizer), Pfizer Inc. (NYSE stock code: PFE), Biogen Inc. (NASDAQ stock code: BIIB) and Eli Lilly and Company (NYSE stock code: LLY), as well as leading domestic biopharmaceutical companies. Our core R&D team is led by Dr. TAN Xiangyang (譚向陽), who has over 30 years’ experience in the research and development of innovative drugs.

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The composition of our core R&D team may change from time to time in line with normal turnover in organizations, the departure of individual members did not, and are not expected to, materially affect our R&D activities or product pipeline. This is because our R&D system is designed to have a large team of capable scientists and researchers and well-coordinated within a balanced structure to reduce reliance on individual members.

None of our R&D team members currently holds any position in the Remaining Kelun Group. Historically, certain of our R&D team members were initially staffed within the Remaining Kelun Group, as our Company was not established until 2016 as a platform dedicated to innovative drug development within Kelun Group. Since inception, we have grown our platform by recruiting R&D personnel, especially those with experience in ADC development, and at the same time, personnel involved in innovative drug research were transferred from the Remaining Kelun Group to our Group to optimize the business delineation of different members within Kelun Group. No R&D personnel currently employed by the Remaining Kelun Group has any meaningful contribution in the development of our Core Products and other pipeline candidates.

During the Track Record Period and in the ordinary and usual course of business, we engaged certain subsidiaries of the Remaining Kelun Group to provide auxiliary R&D services (the “Auxiliary R&D Procurement Services”), which include process development and optimization, sample purification, crystallization screening, GMP batch release testing and packing material release testing. Our Directors are of the view that such Auxiliary R&D Procurement Services provided by the Remaining Kelun Group are supporting services in nature rather than core R&D activities, the latter of which are conducted within our Company. These services do not affect our ability to operate independently from the Remaining Kelun Group. For details, please see “Relationship with our Controlling Shareholders – Operational Independence” and “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement and Provision of Auxiliary R&D Services.”

The following are the key steps of our R&D process, from project initiation, target validation, drug discovery, preclinical studies, to clinical development:

- ***Project Initiation.*** Before initiating a project, our pipeline committee will conduct a comprehensive analysis based on the latest innovations and medical developments in the relevant therapeutic areas, with an aim to assess the market size, patentability, competitive landscape and potential risks involved in a proposed project.
- ***Target Validation and Drug Discovery.*** We carry out initial experiments and collect evidence to support our target selection rationale. After a target is validated, we conduct further testing on a candidate’s biochemical and biophysical properties, as well as early CMC activities to assess its safety and efficacy profile. At this stage, candidates are further evaluated based on key factors such as scientific rationale, risk and safety, commercial viability, patentability, and upcoming clinical, regulatory and manufacturing plans, to make sure that the final candidate selected is differentiated in the competitive landscape and warrants further investment. Our

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drug discovery capabilities are exemplified by our innovative, proprietary ADC design strategies, such as *Kthiol*, our drug-linker strategy to improve ADC stability and reduce off-target and on-target off-tumor toxicity. These ADC design strategies have enabled us to develop ADCs that effectively treat specific types of cancers, including BC, NSCLC and GI cancers, our major indications of interest.

- ***Preclinical Studies.*** During the preclinical stage, we assess the PK performance, toxicity, pharmacological and safety profile of the drug candidate through *in vitro* and animal studies. For ADC candidates, we specifically conduct antibody/antigen binding studies, *in vitro* cytotoxic measurements, *in vivo* anti-tumor efficacy analysis, among other tests, to optimize and select the proper compounds for further efficacy and safety studies. Our discovery committee supervises the entire R&D progress and conducts regular meetings to monitor and discuss the progress of each drug candidate, makes suggestions on whether to advance a certain drug candidate to the clinical stage, while allocating resources to different projects in the discovery portfolio. It also determines the timeline for IND application and other key development milestones. Meanwhile, our translational medicine team conducts extensive research encompassing a wide range of studies from DMPK, toxicology and biomarker development, to quantitative and clinical pharmacology, which is critical to facilitating the bridging of our drug discovery and preclinical studies with clinical needs, and improving the success rates, time-efficiency and cost-effectiveness of our clinical trials.
- ***Clinical Development.*** During clinical trials, we communicate closely with the trial sites and principal investigators to ensure the clinical trial is conducted in a timely manner and in accordance with the study protocol and good clinical practice (GCP) guidelines, under the supervision of our clinical development committee. We select reputable clinical trial institutions and hospitals based on their quality, resources, experiences, reputation, and availability of experts and patients. Furthermore, our regulatory affairs team oversees the registration strategy and submission of documents required by the relevant regulatory authorities. We also maintain close communication with these authorities, including the NMPA and the FDA, to ensure we are following the regulatory requirements for IND and NDA/BLA approvals.

Collaboration with Third Parties

We are primarily responsible for the R&D of our pipeline assets. Our in-house R&D is supported by the third parties we engage, including auxiliary or administrative services to us by CROs and the Remaining Kelun Group. In addition, we work with third-party collaborators in accordance with responsibilities set out in relevant license and collaboration agreements to conduct certain R&D activities. For details, see “– Our License and Collaboration Arrangements.”

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In addition to conducting our core R&D activities in-house, we also engage reputable CROs to manage, conduct, and support our preclinical research and clinical trials. The services they provide under our supervision primarily include performing data management and statistical analyses, conducting site management, patient recruitment and pharmacovigilance services in our clinical trials, and carrying out laboratory tests and other tasks based on our needs. We select CROs based on various factors, such as professional qualifications, research experience in the related fields, service quality and efficiency, industry reputation, and pricing. Depending on the type of services needed, we enter into service agreements with our CROs on a project-by-project basis, which set out detailed work scope, sample size, procedures, deliverables, timeline and payment schedule. We closely supervise our CROs to ensure their performance in a manner that complies with our protocols and applicable laws, which in turn protects the integrity and authenticity of the data from our trials and studies.

Key terms of our agreements that we typically enter into with our CROs are set forth below.

- **Services.** The CRO provides us with services in the course of our preclinical studies and clinical trials, such as implementing animal studies, providing clinical services, record keeping and report preparation.
- **Term.** The CRO is required to perform its services within the prescribed time limit set out in each work order, usually on a project basis.
- **Payments.** We are required to make payments to the CROs in accordance with a payment schedule agreed by the parties.
- **Intellectual property rights.** We own all intellectual property rights arising from the projects conducted by the CROs within the stipulated work scope.

During the Track Record Period and in the ordinary and usual course of business, we engaged certain subsidiaries of the Remaining Kelun Group to provide auxiliary R&D services (the “Auxiliary R&D Procurement Services”), which include process development and optimization, sample purification, crystallization screening, GMP batch release testing and packing material release testing. Our Directors are of the view that such Auxiliary R&D Procurement Services provided by the Remaining Kelun Group are supporting services in nature rather than core R&D activities, the latter of which are conducted within our Company. These services do not affect our ability to operate independently from the Remaining Kelun Group. For details, please see “Relationship with our Controlling Shareholders – Operational Independence” and “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement and Provision of Auxiliary R&D Services.”

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R&D Facilities

As of the Latest Practicable Date, our R&D activities were primarily conducted in Chengdu, Shanghai, and Beijing in China. Our Chengdu headquarters is home to our technology platforms and research laboratories, which are equipped with state-of-the-art equipment and workspace to support our drug discovery, preclinical and clinical needs. In addition, we have established our Shanghai Clinical Center and Beijing Clinical Center, where we house part of our clinical development team. With the collective efforts of our Chengdu, Beijing and Shanghai team, we are able to efficiently manage our drug development plan, clinical protocol design, regulatory affairs and clinical operations across China.

OUR LICENSE AND COLLABORATION ARRANGEMENTS

We believe that an open and collaborative mindset is crucial to the success of our global strategy. Along each step of our drug development plans – from drug discovery to commercialization – we proactively pursue external collaborations, licensing arrangements and other strategic partnerships to create synergies with our pipeline and technology platforms.

Set forth below is a summary of the major terms from our key license and collaboration agreements.

License and Collaboration Agreement with MSD for SKB264

In September 2021, we entered into an option and collaboration agreement with MSD, which was amended and restated as an exclusive license and collaboration agreement (as may be amended from time to time, the “SKB264 Out-license Agreement”) in May 2022, as MSD exercised the exclusive option to obtain, and pursuant to which we granted to MSD an exclusive, royalty-bearing and sublicensable license to develop, use, manufacture and commercialize (“Exploit”) our TROP2 ADCs, including SKB264 (also known as “MK2870” in MSD’s portfolio) and any other TROP2 ADCs we may develop in the future (the “Licensed Compounds”), and products containing one or more such TROP2 ADCs (the “SKB264 Licensed Products”) outside Greater China. As of the Latest Practicable Date, SKB264 was the only TROP2 ADC in our pipeline, and therefore the only TROP2 ADC specifically out-licensed to MSD to date, and we had no specific plans to develop other TROP2 ADCs in addition to SKB264.

MSD, one of our Pre-[REDACTED] investors and an Independent Third Party, is a U.S.-based multinational biopharmaceutical company focused on researching, developing and commercializing innovative pharmaceutical products. MSD is a global healthcare company with deep expertise in the development of innovative oncology drugs. As part of its focus on cancer, MSD is committed to exploring the potential of immuno-oncology with one of the largest development programs in the industry across more than 30 tumor types, while continuing to augment its pipeline, including through strategic collaborations, and developing new generations of drug candidates such as ADCs. We became acquainted with MSD through industry conferences before the two parties explored opportunities for collaboration.

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We also granted MSD a non-exclusive and sublicensable license to use certain of our patents, know-how and clinical data to develop, use and manufacture the Licensed Compounds and the SKB264 Licensed Products within Greater China, solely for the purpose of Exploiting the Licensed Compounds and the SKB264 Licensed Products outside Greater China. In turn, MSD granted to us an exclusive, sublicensable, royalty-free license to use certain of its patents, know-how and clinical data solely for Exploiting the Licensed Compounds and the SKB264 Licensed Products within Greater China. We retain the right to Exploit the Licensed Compounds and the SKB264 Licensed Products for any and all purposes within Greater China. Based on such retained rights, we will continue to advance our clinical development plan for SKB264 in Greater China. For details, see “– Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan.” Each party shall have the right to use all clinical data and results generated from SKB264’s clinical trials to support the development, manufacture and commercialization of the Licensed Compounds or SKB264 Licensed Products outside Greater China (in the case of Merck) and within Greater China (in the case of our Company).

We and MSD have established a Joint Steering Committee (the “JSC”) to discuss the overall coordination and oversight of the activities under the SKB264 Out-license Agreement. The JSC will endeavor to make decisions by consensus, with each of MSD and us having one vote. If consensus is not reached by the parties’ representatives pursuant to such vote, then the matter may be escalated by either party to designated executives of both MSD and us with appropriate decision making authority for resolution. In the event the designated executives are unable to resolve the issue within 30 days, then we shall generally have the final decision-making authority with respect to all matters solely pertaining to Greater China, and MSD shall generally have the final decision-making authority with respect to all matters not solely pertaining to Greater China.

Pursuant to the SKB264 Out-license Agreement, we and MSD have agreed to a study development plan, which may be amended from time to time, to govern the research, development, testing and conduct of certain clinical trials and CMC activities, including evaluating the potential of SKB264 as a monotherapy and in combination with Keytruda for selected solid tumors and advanced NSCLC. We have agreed to continue to be the sponsor of the following global clinical trials, as we had already commenced such trials before the SKB264 Out-license Agreement was signed: (i) continue the ongoing global phase 2 dose expansion study of SKB264 (the “Ongoing SKB Clinical Trial”), which is part of our global phase 1/2 trial of SKB264 as monotherapy for selected advanced solid tumors, and (ii) conduct two basket studies (the “Basket Studies”), namely (A) the global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors and (B) the standalone NSCLC basket study of SKB264 as monotherapy or combination therapies. MSD may request that the Ongoing SKB Clinical Trial and Basket Studies be transferred to itself, as they have the right and responsibility to develop and commercialize SKB264 outside Greater China.

In the event MSD elects to exercise such right, the parties shall negotiate and agree to a transition plan setting forth each party’s obligations in connection with the transfer the details of the transition plan being coordinated and organized by a joint development committee. The joint development committee, a sub-committee under the JSC, is responsible for determining

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the details of the transition plan, and coordinate and oversee the transition. If we continue to conduct such trials, MSD shall make quarterly payments to us based on a study budget stipulated under the agreement, which may be adjusted from time to time, upon our provision of interim data package with progress of these clinical trials. We do not anticipate any negative implications if MSD elects to exercise such rights.

In the event that MSD determines that any regulatory filings (other than those that we have already obtained for the Ongoing SKB Clinical Trial and Basket Studies) outside Greater China are required for any activities hereunder, including INDs, NDAs and other marketing authorizations (as applicable), then as between the parties, MSD shall (i) have the sole right, in its discretion, to obtain such regulatory filings and (ii) be the owner of all such regulatory filings. Upon MSD's request, we shall transfer all regulatory filings for SKB264 that we own or control outside Greater China, including any INDs, NDAs and other marketing authorizations (as applicable), to MSD, provided that, to the extent necessary, we shall retain title to such regulatory filings associated with the Ongoing SKB Clinical Trial and/or a Basket Study until its completion or as of the time MSD elects to assume responsibility for such study. Save as disclosed in this paragraph, we retain the sole right to obtain any regulatory filings and be the owner of all such regulatory filings within Greater China.

In partial consideration of the SKB264 Out-license Agreement, we are eligible to receive four one-time payments totaling up to US\$102.0 million, of which US\$47.0 million had been paid as of the Latest Practicable Date. In addition, MSD agrees to make quarterly payments in connection with SKB264's ongoing research and development activities, the amounts of which are pre-determined and set forth in the agreement, based on a budget agreed between MSD and us. Such budget reflects the costs expected to be incurred by us in performing the R&D activities we have undertaken in relation to SKB264's global clinical trials. To date, we had received a total of US\$81.0 million in quarterly payments. Further, we are entitled to future payments up to an aggregate of (i) US\$380.0 million upon the achievement of specified development milestones by MSD, and (ii) US\$780.0 million upon the achievement of sales-based milestones by MSD. As of the Latest Practicable Date, no milestone payments had become due under this agreement. MSD also agrees to pay us tiered royalties ranging from mid-single-digit to low-double-digit percentage on future annual net sales of the SKB264 Licensed Products outside Greater China, on a product-by-product and country-by-country basis, subject to certain adjustments, until the expiration of the later of (i) the last-to-expire valid patent claim to the applicable SKB264 Licensed Products in a given country; or (ii) a period of ten years following the first commercial sale of the applicable SKB264 Licensed Products in such country.

As of the Latest Practicable Date, the patents we had licensed to MSD included, but are not limited to, one granted patent in China and three pending patent applications (one in China, one in the U.S., and one under the PCT) which we consider material to SKB264's development and commercialization and comprehensively cover SKB264's structure, formulation, method of preparation and use. For details, see "– Intellectual Property." We remain the owner of these licensed patents, while MSD is licensed to utilize these patents owned by us to Exploit the Licensed Compounds and Licensed Products outside Greater China. Inventions arising from

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the performance of the SKB264 Out-license Agreement (and any intellectual property rights therein) shall be owned in accordance with inventorship as determined under U.S. patent laws, regardless of where the activities occurred. Each party has the first right to file applications for patent rights invented and owned by itself, upon appropriate consultation with the other party. As we retained the right to Exploit the Licensed Compounds and SKB264 Licensed Products within Greater China, any invention arising from clinical trials conducted solely by us in Greater China would be owned by us. In addition, MSD has the first right to file patent applications under the name of both parties for patent rights jointly invented and owned by MSD and us, and the first right, but not the obligation, to prosecute and maintain, upon appropriate consultation with us, such joint patent rights worldwide.

Unless terminated earlier in accordance with its terms, the SKB264 Out-license Agreement will remain in effect until expiration of all royalty obligations, upon which all licenses granted to MSD under the agreement shall become fully paid-up, perpetual and irrevocable, and all licenses granted to us by MSD shall become perpetual and irrevocable. MSD has the right to terminate the SKB264 Out-license Agreement at any time, in its sole discretion, by giving us a 60 days’ advance written notice, in which case each party shall pay all amounts then due and owing as of the termination date. In general, either party may terminate this agreement (i) if the other party is in breach of its material obligations under the agreement, within 60 days after notice from the other party requesting cure of the breach, or (ii) in the event of the other party’s bankruptcy, reorganization, liquidation, receivership and similar proceedings. If MSD is entitled to terminate the agreement as a result of our material breach, it may by written notice elect to continue the agreement, in which case: (i) any payments due to us under the SKB264 Out-license Agreement after the date of such written notice (including milestone payments and royalties) shall be reduced to 60% of the initial amount, and (ii) all other terms and conditions of the SKB264 Out-License Agreement shall continue in full force and effect.

License and Collaboration Agreement with MSD for SKB315

In June 2022, we entered into a collaboration and license agreement with MSD, under which we granted to MSD an exclusive, royalty-bearing, sublicensable license to develop, use, manufacture and commercialize (“Exploit”) SKB315, our CLDN18.2 ADC, and products based on SKB315 (the “SKB315 Licensed Products”) globally (the “SKB315 Out-license Agreement”).

We also granted MSD an exclusive and sublicensable license to use our patents and know-how relating to SKB315 to Exploit our CLDN18.2-directed antibodies for medical diagnosis globally, to the extent useful for Exploiting SKB315 and SKB315 Licensed Products. We retain all rights to (i) perform our obligations under the SKB315 Out-license Agreement, and (ii) utilize our technologies, including know-how, patents, and linker and payload technologies, for antibodies or ADC compounds that are not directed to CLDN18.2.

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Pursuant to the SKB315 Out-license Agreement, we shall carry out certain activities in support of the clinical development of SKB315 and SKB315 Licensed Products, under the oversight and direction of a joint steering committee ("JSC") and pursuant to a collaboration plan which may be amended by the JSC from time to time (the "Collaboration Plan").

The JSC will endeavor to make decisions by consensus, with each of MSD and us having one vote. If consensus is not reached by the parties' representatives pursuant to such vote, then the matter may be escalated by either party to designated executives of both MSD and us with appropriate decision making authority for resolution. As of the Latest Practicable Date, the Collaboration Plan included an ongoing phase 1a clinical trial of SKB315 in China. We are entitled to reimbursement from MSD for the reasonable and documented costs we incur in performing such development activities, subject to a collaboration budget which may be reviewed and amended by the JSC from time to time. As of the Latest Practicable Date, we had received reimbursement of US\$1.96 million from MSD.

Except as expressly provided in the Collaboration Plan, MSD shall have the right and operational responsibility to develop and commercialize SKB315 globally, subject to other applicable terms set forth in the SKB315 Out-license Agreement. Notwithstanding the foregoing, MSD shall discuss with us in good faith with respect to our co-promotion rights for SKB315 in China. Upon MSD's request, we shall transfer all regulatory filings for SKB315 that we own or control, including any INDs, NDAs and other marketing authorizations (as applicable), to MSD.

In partial consideration of the SKB315 Out-license Agreement, MSD paid us an upfront payment of US\$35.0 million in September 2022. We are eligible to receive future milestone payments, conditioned upon the achievement of specified development and regulatory milestones, up to an aggregate amount of US\$416.0 million. Further, we are entitled to future milestone payments of up to an aggregate of US\$485.0 million, conditioned upon the achievement of specified sales-based milestones. As of the Latest Practicable Date, no milestone payments had become due under this agreement. MSD also agrees to pay us tiered royalties ranging from mid-single-digit to low-double-digit percentage on future annual net sales of the SKB315 Licensed Products, on a product-by-product and country-by-country basis, subject to certain adjustments, until the expiration of the later of (i) the last-to-expire valid patent claim to the applicable SKB315 Licensed Products in a given country; or (ii) for a period of ten years following the first commercial sale of the applicable SKB315 Licensed Products in any such country.

Inventions arising from the performance of the SKB315 Out-license Agreement (and any intellectual property rights therein) shall be owned in accordance with inventorship as determined under U.S. patent laws. MSD has the first right to file patent applications under the name of both parties for the patent rights jointly owned by MSD and us. MSD shall have the first right, but not the obligation, to prosecute and maintain, upon appropriate consultation with us, such joint patent rights worldwide.

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Unless terminated earlier in accordance with its terms, the SKB315 Out-license Agreement will remain in effect until expiration of all royalty obligations, upon which all licenses granted to MSD under the agreement shall become fully paid-up, perpetual and irrevocable. MSD has the right to terminate the SKB315 Out-license Agreement at any time, in its sole discretion, by giving us a 60 days’ advance written notice, in which case each party shall pay all amounts then due and owing as of the termination date, including but not limited to the development costs we may have incurred consistent with the Collaboration Plan. In general, either party may terminate this agreement (i) if the other party is in breach of its material obligations under the agreement, within 60 days after notice from the other party requesting cure of the breach, or (ii) in the event of the other party’s bankruptcy, reorganization, liquidation, receivership and similar proceedings. If MSD is entitled to terminate the agreement as a result of our material breach, it may by written notice elect to continue the agreement, in which case: (i) any payments due to us under the SKB315 Out-license Agreement after the date of such written notice (including milestone payments and royalties) shall be reduced to 60% of the initial amount, and (ii) all other terms and conditions of the SKB315 Out-License Agreement shall continue in full force and effect.

License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets

In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets for the treatment of cancer. Under this agreement, we granted to MSD exclusive global licenses to research, develop, manufacture and commercialize multiple preclinical ADC assets (“Licensed ADCs”) and exclusive options to obtain additional exclusive licenses to certain other preclinical ADC assets (“Option ADCs”). We retain the right to research, develop, manufacture and commercialize certain Licensed ADCs and Option ADCs for China, Hong Kong and Macau.

MSD paid us a non-refundable upfront payment of US\$175.0 million in March 2023. We are eligible to receive future milestone payments, conditioned upon the achievement of specified development, regulatory and sales-based milestones, up to an aggregate amount of US\$9.3 billion, if all candidates achieve regulatory approval and we do not retain mainland China, Hong Kong and Macau rights for the Option ADCs, plus tiered royalties on net sales for any commercialized ADC product. As of the Latest Practicable Date, no milestone payments had become due under this agreement.

Inventions arising from the performance of this agreement (and any intellectual property rights therein) shall be owned in accordance with inventorship as determined under U.S. patent laws. MSD has the first right to file patent applications under the name of both parties for the patent rights jointly owned by MSD and us, and the first right, but not the obligation, to prosecute and maintain, upon appropriate consultation with us, such joint patent rights worldwide. Unless terminated earlier in accordance with its terms, this agreement will remain in effect until expiration of the respective royalty obligations, upon which all licenses granted to MSD under the agreement shall become fully paid-up, perpetual and irrevocable. MSD has the right to terminate this agreement in whole or in part with respect to a given collaboration program at any time, in its sole discretion, by giving us a 60 days’ advance written notice,

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provided that no termination shall become effective until we receive the aforementioned upfront payment. Each party shall pay all amounts then due and owing as of the termination date and MSD shall make payment to us for all applicable costs we incurred up to the termination date and not yet paid for (if any). In general, either party may terminate this agreement (i) if the other party is in breach of its material obligations under the agreement, within 60 days after notice from the other party requesting cure of the breach, or (ii) in the event of the other party’s bankruptcy, reorganization, liquidation, receivership and similar proceedings. If MSD is entitled to terminate this agreement as a result of our material breach, it may by written notice elect to continue the agreement, in which case: (i) any payments due to us under this agreement after the date of such written notice shall be reduced to 60% of the initial amount, and (ii) all other terms and conditions of this agreement shall continue in full force and effect.

Cooperative Development Agreement with Levena for A166

In March 2014, Kelun Research Institute entered into a cooperative agreement with Concartis, Inc. (“Concartis”) to jointly develop A166, our HER2 ADC (as amended and supplemented, the “A166 Co-development Agreement”). An amendment agreement was signed in December 2020 among our Company, Kelun Research Institute, Levena (Suzhou) Biopharma Co., Ltd. (“Levena”), Concartis, and Sorrento Therapeutics, Inc. (NYSE: SRNE), pursuant to which (i) we accepted and assumed all the rights and obligations of Kelun Research Institute, and (ii) Levena accepted and assumed all the rights and obligations of Concartis under the A166 Co-development Agreement. Both Concartis and Levena are affiliates of Sorrento Therapeutics, Inc., an Independent Third Party and U.S.-based clinical and commercial stage biopharmaceutical company specialized in the development of novel cancer therapies.

Pursuant to the A166 Co-development Agreement, we have the global right to develop, manufacture and commercialize A166, including the right to seek regulatory approvals for A166 in China and all other jurisdictions. In addition, Levena agrees to provide all necessary technical support and assistance throughout the key stages of A166’s development, including granting us a global, non-exclusive license, without the right to further grant sublicenses, to utilize certain patents (registered or pending) and know-how related to its linker and payload technologies which are used for A166’s development. We take a leading role in, and are primarily responsible for, all key stages of A166’s development and commercialization, from preclinical studies, clinical trials, manufacturing, to regulatory approval and commercialization. The intellectual property and know-how arising from A166 Co-development Agreement shall be co-owned by Levena and us. We shall be the patentee and the first inventor of all patents. The second inventor shall be a designated personnel of Levena, and the remaining inventors shall be determined by both parties. As of the Latest Practicable Date, we were the patentee of the four material patents and patent applications relating to A166 as disclosed under “– Intellectual Property.”

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In consideration of the A166 Co-development Agreement, we agreed to pay Levena license fees up to a total of RMB9.5 million, payable in installments upon the achievement of specified development and regulatory milestones, of which RMB6.5 million had been paid as of the Latest Practicable Date. Upon commercialization, we are also required to pay Levena low single-digit royalties on the annual sales of A166 for a period of ten years after the first commercial sale. Furthermore, either party may seek collaborators to further develop and commercialize A166 outside China and share any economic gains (such as upfront payments, milestone payments and royalties) arising from such overseas collaborations. We are entitled to 65% or 70% of such economic gains, the exact ratio variable based on Levena’s efforts in identifying the collaborators.

Any dispute arising from or in connection with the co-development shall be first settled through mutual negotiation between the parties. Where the dispute cannot be successfully settled, it shall be submitted to the designated venue for arbitration.

The A166 Co-development Agreement will remain valid and binding until December 2033, after which the rights granted to us to utilize the patents and know-how related to Levena’s linker and payload technologies shall become perpetual and fully paid up. The agreement may be terminated earlier for the following reasons: (i) upon either party’s material breach, (ii) we fail to fulfill our payment obligations after Levena’s notice, (iii) we determine to terminate the development and commercialization of A166, and (iv) by the parties’ agreement upon consultation. If the collaboration is terminated due to Levena’s failure to fulfill its contractual obligations, Levena shall refund 50% of any license fees we had paid. In the event of a breach of contract, the defaulting party shall bear all losses incurred by the other party as a result of its breach.

Collaboration and Licensing Agreement with Harbour BioMed for A167

In August 2018, we entered into a strategic collaboration and licensing agreement with Harbour BioMed, under which we granted to Harbour BioMed an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A167 (also known as “HBM9167” in Harbour BioMed’s portfolio), our PD-L1 mAb, outside Greater China (as amended and supplemented, the “A167 Out-license Agreement”). Harbour BioMed, an Independent Third Party, is a biopharmaceutical company engaged in the discovery and development of differentiated antibody therapeutics in immunology and oncology disease areas.

Under the A167 Out-license Agreement, Harbour BioMed was granted the rights to use our patents and know-how relating to A167 to develop, manufacture and commercialize monotherapies or combination therapies based on A167 (the “A167 Licensed Products”) outside Greater China, subject to certain rights we have retained to develop combination therapies based on A167 and any agent(s) developed by us or in which we own at least a 50% interest. We also granted Harbour BioMed the right to use such patents and know-how relating to A167 within Greater China for limited purposes, including (i) to facilitate the development and commercialization of the A167 Licensed Products outside Greater China, and (ii) to develop, manufacture and commercialize combination therapies based on A167 and any agent(s) developed, or wholly owned, by Harbour BioMed.

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In partial consideration of the A167 Out-license Agreement, Harbour BioMed paid us an upfront payment of US\$6.0 million in August 2018. In addition, we are eligible to receive payments upon the achievement of specified development, regulatory and commercial milestones up to US\$351.0 million, of which US\$2.0 million had been received as of the Latest Practicable Date. We will also be eligible to receive tiered royalties as a high single-digit to low double-digit percentage of the annual net sales of the A167 Licensed Products outside Greater China, subject to certain adjustments, with a royalty term of 15 years commencing upon the first commercial sale of the A167 Licensed Products.

Either party shall own any invention made solely by itself or its agents (including any know-how, data and other information relating to such invention) arising from the performance of the A167 Out-license Agreement and all intellectual property rights therein. Any joint invention shall be co-owned by Harbour BioMed and us, and either party is entitled to utilize such joint invention and to grant non-exclusive licenses based on such invention to third parties. Issuance of exclusive licenses based on joint inventions requires the mutual consent of both parties.

Unless terminated earlier pursuant to its terms, the A167 Out-license Agreement will remain in effect until the expiry of the royalty term. Either party may terminate the A167 Out-license Agreement with a 60 days’ prior written notice in the event of (i) the other party’s bankruptcy, insolvency or termination of business (other than for the purpose of reorganization or merger), or (ii) the other party’s uncured material breach of the A167 Out-license Agreement.

Any disputes arising out of the A167 Out-license Agreement shall be notified by the party raising the dispute to the other party in writing. After receiving such notice, both parties shall schedule a meeting to resolve the dispute. If the dispute cannot be resolved, or such meeting is not held, within a period of time, then the dispute may be submitted to the Hong Kong International Arbitration Centre for final resolution.

See also “Connected Transactions – Non-exempt Continuing Connected Transactions – Licensing Agreement” for details on our patent and technology in-license agreement with Kelun Research Institute, a wholly-owned subsidiary of Kelun Pharmaceutical, in relation to A167, pursuant to which Kelun Research Institute is entitled to a single-digit percentage of the net sales revenue derived from the sale of A167 after its commercialization.

Collaboration and License Agreement with Ellipses for A400

In March 2021, we entered into a collaboration and license agreement with Ellipses, under which we granted to Ellipses an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A400 (also known as “EP0031” in Ellipses’s portfolio), our RET inhibitor, in all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand (collectively, the “Licensed Territory”) (as amended and supplemented, the “A400 Out-license Agreement”). Ellipses, an Independent Third Party, is a U.K.-based international drug development company focused on the development of innovative cancer treatments.

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Under the A400 Out-license Agreement, Ellipses was granted the rights to use our patents, know-how and other intellectual property rights relating to A400 to develop, manufacture and commercialize products based on A400 (the "A400 Licensed Products") in the Licensed Territory, including the rights to access and use our regulatory submissions and clinical data generated outside the Licensed Territory. We also granted Ellipses a non-exclusive license to use certain of our patents, know-how and other intellectual property rights to manufacture the A400 Licensed Products outside the Licensed Territory, solely for commercializing the A400 Licensed Products in the Licensed Territory. In turn, Ellipses granted to us an exclusive, fully paid-up, sublicensable license to use its patents and know-how outside the Licensed Territory as well as an exclusive license to its clinical data inside the Licensed Territory, solely for the purposes of developing, manufacturing and commercializing the A400 Licensed Products outside the Licensed Territory.

Ellipses and we have established a joint development committee ("JDC") to oversee the development and commercialization of the A400 Licensed Products. We shall, in coordination with Ellipses via the JDC, manage and perform, or procure the performance of, preclinical development activities and experiments as the JDC shall agree are necessary for the IND applications (or any equivalent filings) Ellipses intends to make in the Licensed Territory. Pursuant to A400 Out-license Agreement, if we intend to discontinue or abandon the development or commercialization of A400 or its relevant rights outside the Licensed Territory, Ellipses shall have exclusive first right of refusal, for a period of at least 90 days, in which to acquire any such rights from us.

In consideration of the A400 Out-license Agreement, we are entitled to (i) preclinical development payments up to an aggregate amount of US\$2.91 million, payable by installments in accordance with a specified timeline, for our management and oversight of, and costs incurred in, A400's preclinical development activities, including for providing the necessary data and support to facilitate A400's IND filing and maintenance in the Licensed Territory; (ii) technology transfer fee of US\$30.0 thousand for furnishing the manufacturing know-how and performing related analysis; (iii) sharing of revenue as low double-digit percentages of the total payments received by Ellipses in consideration for any sub-license agreement(s), if executed; and (iv) tiered royalties as low-teen percentages of the annual net sales of the A400 Licensed Products, on a product-by-product basis, generally with a royalty term of ten years commencing upon the first commercial sale of the A400 Licensed Products in such country or region, subject to adjustments (such as third-party payment offset) as stipulated between the parties. We had received a total of US\$3.22 million as of the Latest Practicable Date.

Either party shall own any invention made by itself arising from the performance of the A400 Out-license Agreement and all intellectual property rights therein. A patenting sub-committee has been set up to facilitate discussion and decision-making regarding the applications for intellectual property rights in relation to A400 or the A400 Licensed Products, including to resolve intellectual property-related disputes arising from the collaboration.

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Unless terminated earlier in accordance with its terms, the A400 Out-license Agreement will remain in effect until no further payments are due to us, upon which all licenses granted under the agreement shall become perpetual and fully paid-up. Either party may terminate the A400 Out-license Agreement in the event of the other party’s uncured material breach, willful misconduct, fraud, breach of anti-bribery obligations, or gross negligence in relation to its obligation under the agreement. We are also entitled to termination of the A400 Out-license Agreement upon written notice to Ellipses in the event of (i) Ellipses’s failure to exercise commercially reasonable efforts to conduct clinical activities in a timely manner as contemplated by the agreement, unless excusable under specific circumstances, or (ii) Ellipses’s insolvency (other than for the purpose of reorganization or merger), asset possession by competent authorities or persons or likewise.

The JDC facilitates communications between the parties to discuss and perform the development plan. The JDC will endeavor to make decisions by consensus. If the dispute or failure to agree cannot be resolved by the JDC, Ellipses shall generally have the casting vote in respect of such decision to the extent it applies inside the Licensed Territory, and we shall generally have the casting vote in respect of such decision to the extent it applies outside the Licensed Territory. The patenting sub-committee of the JDC will coordinate the filing of patent applications and other matters related to intellectual property, and endeavor to resolve disputes arising therefrom.

Cooperative Development Agreement with Harbour BioMed for SKB378

In May 2019, we entered into a cooperative development agreement with Harbour BioMed (Suzhou) Co., Ltd. (recently renamed NONA BIOSCIENCES (SUZHOU) CO., LTD.), an indirect wholly owned subsidiary of Harbour BioMed, to jointly develop SKB378 (also known as “HBM9378” in Harbour BioMed’s portfolio), our anti-TSLP mAb, utilizing Harbour BioMed’s H2L2 antibody platform and related know-how (as amended and supplemented, the “SKB378 Co-development Agreement”).

Under the SKB378 Co-development Agreement, at the drug discovery and development stage, Harbour BioMed and we each assume certain responsibilities in SKB378’s preclinical and clinical studies, as well as regulatory affairs, pursuant to a co-development plan agreed between the parties. Both parties take an active role in advancing SKB378’s global clinical development plan. Harbour BioMed is primarily responsible for seeking IND approval and conducting clinical trials for SKB378 in Greater China, North America and certain Asia-Pacific countries, while we carry out the same responsibilities in all other countries and regions, including the E.U. The parties equally share all costs related to SKB378’s clinical development plans across territories, including expenses associated with the application for IND and marketing approvals in the respective jurisdiction.

BUSINESS

Harbour BioMed and we have established a joint development committee ("JDC") to oversee the development and commercialization of SKB378. As SKB378 approaches commercialization, Harbour BioMed shall take a leading role in seeking and obtaining marketing approvals for SKB378 in North America and certain Asia-Pacific countries (excluding Greater China), while we shall take a leading role in doing so in all other countries and regions, including Greater China and the E.U. Each party is obligated to provide the necessary support and assistance, as reasonably requested by the other party, to facilitate the requisite regulatory submissions and communications. Subject to certain adjustments under limited circumstances, the parties equally share all net profits arising from SKB378's future commercial sales within the term of the SKB378 Co-development Agreement.

Harbour BioMed granted us a license to use certain of its background intellectual property rights, including know-how related to its H2L2 antibody platform, to enable SKB378's joint development. Any intellectual property and know-how arising from the collaboration under the SKB378 Co-development Agreement shall be co-owned by Harbour BioMed and us. Either party is entitled to utilize intellectual property rights related to A378 to develop derivative products or combination therapies upon notifying the other party.

In partial consideration of the SKB378 Co-development Agreement, Harbour BioMed agreed to reimburse us for certain discovery and preclinical R&D activities. In turn, we agreed to reimburse Harbour BioMed for certain costs it incurred in relation to SKB378's IND application and clinical studies in Greater China, payable upon the achievement of specified clinical development and regulatory milestones in Greater China.

Either party is entitled to terminate the SKB378 Co-development Agreement under certain circumstances, including: (i) upon written agreement by the parties, (ii) with a 30 days' prior written notice in the event of the other party's uncured material breach, and (iii) material delays or significant decline of asset value due to technical feasibility issues which cannot be resolved by the parties. If one party chooses to opt out of SKB378's co-development plan in specific region(s), upon or before the termination of the SKB378 Co-development Agreement, the remaining party is entitled to assume all rights previously granted to the departing party within the respective region(s), subject to certain conditions and provided that the departing party is reimbursed in accordance with the relevant financial terms.

The JDC will endeavor to make decisions by consensus. If a dispute or failure to agree arises which cannot be resolved by the JDC, the chairman of the board or chief executive officer of each party shall confer in a timely manner. In the event the designated representatives are unable to resolve the issue, then Harbour BioMed shall generally have the final decision-making authority with respect to the matters pertaining to North America and certain Asia-Pacific countries (excluding Greater China), while we shall have the final decision-making authority with respect to all matters pertaining to all other countries and regions, including Greater China and the E.U.

BUSINESS

MANUFACTURING

To date, our manufacturing activities are primarily limited to supporting our drug development process. For more details, see “– Research and Development – R&D Facilities.” Anticipating future commercialization, we are building up our own cGMP-compliant pilot-scale and commercial-scale manufacturing capabilities to ensure delivery of high-quality drug products. We also engaged, and will continue to engage, industry-recognized CMOs to supplement our in-house capacity so as to enhance efficiency and reduce operational and regulatory compliance costs.

Manufacturing Facilities

Our manufacturing facilities are designed to meet the manufacturing challenges associated with the production of complex molecules such as ADCs, which require integrated manufacturing capabilities that span across biologics and small molecules, and a dedicated manufacturing environment that allows the safe manipulation of highly active agents. Our manufacturing facilities are designed in compliance with the NMPA and FDA’s regulatory requirements and cGMP standards in China, the U.S. and Europe. As of December 31, 2022, our manufacturing team consisted of over 180 employees.

Our main manufacturing site in Chengdu has a total floor area of over 10,600 m², including approximately 9,400 m² designated for commercial-scale production. See “– Properties.” It is one of the few facilities in China with cGMP-compliant, end-to-end capabilities covering the entire development lifecycle of ADCs from cell culture and purification, antibody production, syntheses of payloads and linkers, ADC conjugation to formulation, fill and finish.

Our existing commercial-scale manufacturing facilities mainly consist of: (i) cell culture and purification facilities equipped with two 2,000 L single-use bioreactors; (ii) antibody formulation facilities equipped with annual production capacity to produce 60 batches (or 750,000 vials) of freeze-dried formulation or 100 batches (or 2.6 million vials) of injectable solutions; (iii) payload-linker synthesis facilities with annual production capacity of 15 batches; (iv) ADC conjugation facilities equipped with one 300 L ADC conjugation tank with a maximum annual production capacity of 40 batches of ADC drug substance; and (v) ADC formulation facilities with annual production capacity of 45 batches (or 900,000 vials) of freeze-dried ADCs or 60 batches (or 1.2 million vials) of injectable ADCs.

We have set up a professional manufacturing team with management personnel with decades of work experience in leading pharmaceutical companies, such as Eli Lilly, BMS and Akeso. We are also training up young talents to enhance our in-house technical capabilities. In anticipation of the increased demand upon commercialization, we are actively evaluating the addition of new manufacturing facilities and the expansion of existing manufacturing facilities. For our cell culture and purification unit, we plan to install one additional 2,000 L single-use bioreactor, bringing our total in-house capacity to 6,000 L. Going forward, we will continue to enhance our manufacturing capabilities to ensure that we have sufficient capacity for our commercial-scale production. See also “Future Plans and [REDACTED].”

BUSINESS

CMOs

We currently outsource certain manufacturing activities, primarily the production of small molecules, to industry-recognized CMOs in China, and we intend to continue doing so in the future. We believe it is cost-effective and efficient to engage CMOs for certain manufacturing activities as it reduces the capital expenditure required for setting up and maintaining the necessary production lines, and allows us to focus on the core processes of ADC manufacturing.

We select CMOs by taking into account a number of factors, such as their manufacturing capacity and qualifications, geographic proximity and track record, applicable regulations and guidelines, as well as our R&D objectives and the specifications set by our collaborators. To monitor and evaluate the services of our CMOs, we conduct quality assurance audit programs to ensure, among other criteria, full compliance of our CMOs with the relevant regulatory requirements.

Following a rigorous consultation and bidding process, we enter into formal agreements with the selected CMOs. Key terms of our agreements that we typically enter into with our CMOs are set forth below.

- **Services.** The CRO provides us with manufacturing services according to the types of deliverables, location, unit price, volume and requested delivery date specified by us.
- **Quality control and inspections.** We are entitled to conduct on-site audits and regular inspections to ensure compliance of our CMOs with the relevant cGMP and regulatory requirements.
- **Payments.** We are required to make payments to the CMOs in accordance with the payments schedule set forth in the agreement, which is typically linked to the stages of the manufacturing process and the deliverables we receive.
- **Intellectual property rights.** We own all intellectual property rights arising from the outsourced manufacturing processes.
- **Remedies for non-conforming products.** We are entitled to remedies for products that fail to conform to our specifications. The CMOs are required to replace the non-conforming products and compensate us for any direct losses due to the delay.

For risks relating to CMOs, see “Risk Factors – Risks Relating to Dependence on Third Parties – We may rely on third parties to manufacture our drug products for clinical development and commercial sales. Our business could be harmed if these third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality or price levels.”

BUSINESS

QUALITY CONTROL

We operate a comprehensive quality control system which extends across all key stages of the R&D, manufacturing and commercialization processes. This system is established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. We pay close attention to the evolving cGMP standards and regulatory developments in these target markets and update our internal procedures accordingly, striving for the highest international standards in patient safety and regulatory compliance. Furthermore, our quality expert team are actively involved in the discussion and promulgation of regulations and guidelines in China, which attests to our recognized expertise in the respective fields. For example, we took an active role in the drafting of the “Biological Products (mAb)” section of the Chinese GMP Implementation Guide (Re-issued) (中國GMP實施指南(再版)《生物製品(單克隆抗體)》部分) in 2022.

As of December 31, 2022, our quality management team comprised over 150 members, including 136 overseeing our manufacturing process and 17 overseeing our preclinical studies and clinical trials. They oversee the quality systems covering all key stages of our drug development process, from R&D, manufacturing to commercialization, including discovery, preclinical research and discovery, clinical trials, procurement, supply chain, process development, production, warehousing, delivery and recalls.

We have established comprehensive quality control and quality assurance procedures to ensure that our manufacturing processes comply with relevant regulatory requirements and our internal quality standards. We select qualified raw material suppliers, and recruit manufacturing and quality management personnel based on a strict set of criteria. We regularly inspect our facilities and equipment to ensure that our processes, methods, programs and equipment function properly. We closely monitor the manufacturing environment, especially key parameters such as microbial levels, temperature, and humidity. We generally perform overall inspections every year and engage external experts and counsel to conduct quality audit. We strive to upgrade and improve our comprehensive quality control system, benchmarking against the highest international standards adopted by pharmaceutical MNCs, to ensure patient safety and regulatory compliance.

COMMERCIALIZATION

We are well-positioned to develop our commercialization infrastructure and market access, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network. Guided by Kelun Pharmaceutical’s leading industry position, strong brand image and profound resources as one of China’s largest and most established pharmaceutical companies, we are planning to develop our own commercialization team and network, with an initial focus on Class III hospitals and leading physicians across China’s extensive local markets. We will also continue to refine our commercialization strategies for each late-stage drug candidate, first prioritizing therapeutic areas with medical needs in China, such as BC, NSCLC and GI cancers, while offering synergistic treatment options enabled by our diverse pipeline to optimize patient outcome.

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Based on the expected approval timeline of each late-stage project in our pipeline, we expect to receive conditional marketing approval from the NMPA for A167 (PD-L1 mAb), our first innovative drug in NDA registration stage, in the second half of 2023 or the first half of 2024. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 in the China market in the second half of 2024 or the first half of 2025. In anticipation of these upcoming milestones, we are actively recruiting talent with a strong background in oncology, especially in BC, NSCLC, GI cancers and NPC, our lead indications for these late-stage assets. We plan to set up a fully-fledged commercialization team by the end of 2023 to oversee and coordinate the sales and marketing of A167, as well as the pre-marketing preparation for SKB264 and A166, laying the groundwork for rapid commercial-scale distribution upon these two ADCs’ anticipated NDA approval by the NMPA. Globally, we will continue to pursue a flexible strategy to capture the commercial value in major international markets, through forging synergistic license and collaboration opportunities worldwide.

BUSINESS DEVELOPMENT

We have established robust, cross-border business development capabilities with local presence across multiple jurisdictions, from Chengdu, Beijing and Shanghai in China to New Jersey in the U.S. Our business development team is led by seasoned professionals with decades-long experience and insights in sourcing and executing licensing deals and collaborations. They work closely with our scientists and team leaders on each project, and are involved as early as the drug discovery stage to identify and capture partnership opportunities.

Our business development competencies are exemplified by a proven track record in forging strategic partnerships worldwide, which in turn reflect the increasing recognition we have received from peers and leaders in the global biopharmaceutical industry. Notably, we have successfully negotiated nine out-license agreements to date, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical MNC. Our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world’s largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth. See also “– Our Development Strategies – Continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline.”

BUSINESS

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business, and we are committed to the development and protection of our intellectual properties. Our future commercial success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 74 issued patents in China, (ii) 21 issued patents in the U.S., (iii) 52 issued patents in other jurisdictions, and (iv) 255 pending patent applications, including 100 in China, 14 in the U.S., 16 under the Patent Cooperation Treaty (PCT) and 125 in other jurisdictions. The patents granted to, or under application by, our Company cover all material aspects of our Core Products.

As of the Latest Practicable Date, with respect to our two Core Products, SKB264 and A166, we owned five issued patents in China and eight issued patents in other jurisdictions, as well as 21 pending patent applications, including six in China, five in the U.S., three under the PCT and eight in other jurisdictions. With these patents, we own both SKB264 and A166 as differentiated drug molecules as these patents comprehensively cover their structure, formulation, method of preparation and use.

The following table summarizes the details of the material granted patents and patent applications in connection with our Core Products. For details, please see “Appendix VII – Statutory and General Information – Further Information About our Business – 2. Our Intellectual Property Rights - (b) Patents.”

Related Product	Scope of Patent Protection	Category	Patent Number/ Patent Application Number	Jurisdiction	Patent Holder/ Applicant	Expiration Year*
SKB264	Camptothecin derivatives and their water-soluble prodrugs, pharmaceutical compositions containing them, their preparation methods and uses	Invention	2020800065387	China	Our Company	N/A**
SKB264	Biologically active substance conjugate and its preparation method and use	Invention	2018800695435	China	Our Company	2038
SKB264	Use of medicament in treatment of tumor disease	Invention	US16758980	U.S.	Our Company	N/A**
A166	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application	Invention	WO2022228497A1	PCT	Our Company	N/A**
A166	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application	Invention	2015108240648	China	Our Company	2035
A166	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application	Invention	2016800367605	China	Our Company	2036

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Related Product	Scope of Patent Protection	Category	Patent Number/ Patent Application		Patent Holder/ Applicant	Expiration Year*
			Number	Jurisdiction		
A166	Use of anti-HER2 antibody-drug conjugates in the treatment of cancer	Invention	2019800186355	China	Our Company	N/A**
A166	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application	Invention	JP2017566133	Japan	Our Company	2036

* Patent expiration does not include any applicable patent term extensions

** Pending patent application.

As of the Latest Practicable Date, we owned two issued Chinese utility model patents for our various innovative technologies that are utilized throughout our drug development and manufacturing process, including (i) a device for detecting oxygen level in ampules (No. 2019214180811) and (ii) a buffer preparation system (No. 202121433214X). These utility model patents have a term of ten years from the date of filing and are expected to expire in and after 2029.

The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction 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 jurisdiction 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. See “Risk Factors – Risks Relating to Our Intellectual Property Rights” for a description of risks related to our intellectual property.

We conduct our business under the brand name of “Kelun Biotech” (“科倫博泰”). As of the Latest Practicable Date, we had registered 59 trademarks in China and 59 trademarks in other jurisdictions. We are also the registered owner of one domain name.

We enter into license and collaboration agreements and other relationships with biopharmaceutical companies and other industry participants, through which we may grant access to our own intellectual property, or gain access to the intellectual property of others. See “– Our License and Collaboration Arrangements.”

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

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See “Appendix VII – Statutory and General Information – B. Further Information about Our Business – 2. Our Intellectual Property Rights” to this document for further information.

SUPPLIERS AND PROCUREMENT

During the Track Record Period, our suppliers primarily consisted of (i) suppliers of raw materials and consumables for our drug development, (ii) suppliers of equipment and devices for our manufacturing activities and construction service providers for our new facilities, and (iii) CROs, who provide third-party contracting services for research and development.

A majority of our raw materials are widely available, and we are able to purchase them from numerous suppliers around the world according to our product development plans. The raw materials procured for our product candidates primarily include cell culture media, chromatography resins, excipients, packaging materials, nanofiltration and ultrafiltration membranes, bioreactor and single-use bioprocess bags and other ancillary materials used for our research and development activities. We have established stable collaboration relationships with qualified suppliers for raw materials, which we believe have sufficient capacity to meet our demands. Nevertheless, we believe that adequate alternative sources for such supplies exist. To monitor the quality of supplies, we implemented a standardized operating system, setting out the procedures and guidelines for the procurement of raw materials, quality control inspection, warehousing, testing, and storage. In particular, for overseas suppliers, we typically devise a comprehensive procurement plan in advance to ensure sufficient and timely supply. A number of our overseas suppliers have established local branches or subsidiaries in China, which provides more convenience and visibility for our procurement. Meanwhile, we are exploring collaboration opportunities with alternative domestic suppliers, such as for the supply of cell culture media. During the Track Record Period, we did not experience any material shortage or delays in the supply of raw materials.

See also “– Research and Development – Collaboration with CROs” for details on our relationship with the CROs.

For the years ended December 31, 2021 and 2022, our purchases from our largest supplier accounted for 24.4% and 12.0% of our total purchases and our purchases from our five largest suppliers in the aggregate accounted for 48.4% and 38.9% of our total purchases, respectively. During each year of the Track Record Period, Kelun Group (together with Kelun Medicine & Trade Group), was our largest supplier. For further details, please see “Connected Transactions.” The following table sets forth details of our five largest suppliers during the Track Record Period.

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Supplier	Background	Products/ services provided	Commencement of business relationship	Credit terms	Purchase amount <i>(RMB in thousands)</i>	% of total purchases
<i>For the year ended December 31, 2021</i>						
Supplier A	Kelun Group together with Kelun Medicine & Trade Group	R&D service, sales of materials and equipment	2018	N/A*	187,881	24.4%
Supplier B	A China-based company primarily engaged in construction and engineering	Construction	2020	14 days	96,092	12.5%
Supplier C	A China-based company together with its related parties, primarily engaged in sales of pharmaceuticals, technology promotion and application services	R&D service	2020	30 days	37,910	4.9%
Supplier D	A China-based company primarily engaged in wholesale and retail of pharmaceuticals and inspection services	R&D service	2018	15 days	29,116	3.8%
Supplier E	A China-based company primarily engaged in construction and engineering	Construction	2021	14 days	21,983	2.9%
Total					<u>372,982</u>	<u>48.4%</u>

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Supplier	Background	Products/ services provided	Commencement of business relationship	Credit terms	Purchase amount <i>(RMB in thousands)</i>	% of total purchases
<i>For the year ended December 31, 2022</i>						
Supplier A	Kelun Group together with Kelun Medicine & Trade Group	R&D service, sales of materials and equipment	2018	N/A ⁽¹⁾	129,913	12.0%
Supplier C	A China-based company together with its related parties, primarily engaged in sales of pharmaceuticals, technology promotion and application services	R&D service	2020	30 days	120,827	11.1%
Supplier F	A China-based company together with its related parties, primarily engaged in pharmaceutical production, wholesale and retail of pharmaceuticals and inspection services	R&D service	2022	30 days	75,070	6.9%
Supplier B	A China-based company primarily engaged in construction and engineering	Construction	2020	14 days	54,808	5.0%

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Supplier	Background	Products/ services provided	Commencement of business relationship	Credit terms	Purchase amount <i>(RMB in thousands)</i>	% of total purchases
Supplier G	A China-based company together with its related parties, primarily engaged in sales of pharmaceuticals, technology promotion and application services	R&D service	2021	30 days	41,568	3.8%
Total					<u>422,186</u>	<u>38.9%</u>

Note:

- (1) Credit terms are not specified under the relevant contracts.

To the best of our knowledge, except for Kelun Group (together with Kelun Medicine & Trade Group), (i) all of our five largest suppliers during the Track Record Period are independent third parties, and (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest suppliers during the Track Record Period. Kelun Group (together with Kelun Medicine & Trade Group) was also among our five largest customers during the Track Record Period. See also “Financial Information – Material Related Party Transactions.”

CUSTOMERS

During the Track Record Period, our revenue was primarily derived from (i) our license and collaboration agreements with MSD and other licensing partners, and (ii) provision of research and development services to Kelun Group and other third parties. For further details, please see “Financial Information – Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income – Revenue.”

For the years ended December 31, 2021 and 2022, our revenue generated from our largest customer accounted for 61.6% and 90.8% of our total revenue, and revenue from our five largest customers in the aggregate represented over 99.9% of our total revenue in each year. During each year of the Track Record Period, Kelun Group (together with Kelun Medicine & Trade Group) was one of our largest customers. The following table sets forth details of our five largest customers during the Track Record Period.

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Customer	Background	Services	Commencement of business relationship	Credit terms	Revenue contribution (RMB in thousands)	% of total revenue
<i>For the year ended December 31, 2021</i>						
Customer A	Kelun Group together with Kelun Medicine & Trade Group	R&D services	2018	N/A*	19,919	61.6%
Customer B	A European company primarily engaged in innovative drug development	License and collaboration	2020	30 days	11,937	36.9%
Customer C	A China-based company together with its related parties, primarily engaged in drug development and production	R&D services	2021	10 days	328	1.0%
Customer D	A China-based company primarily engaged in the development of innovative drugs	R&D services	2021	10 days	138	0.4%
Total					<u>32,322</u>	<u>100.0%</u>

For the year ended December 31, 2022

Customer E	A US-based company primarily engaged in the development of innovative health solutions	License and collaboration	2021	45 days	730,037	90.8%
Customer A	Kelun Group together with Kelun Medicine & Trade Group	R&D services	2018	N/A ⁽¹⁾	55,950	7.0%
Customer F	A European company primarily engaged in innovative drug development	License and collaboration	2017	30 days	12,749	1.6%
Customer B	A European company primarily engaged in drug development	License and collaboration	2020	30 days	4,659	0.6%

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Customer	Background	Services	Commencement of business relationship	Credit terms	Revenue contribution <i>(RMB in thousands)</i>	% of total revenue
Customer C	A China-based company together with its related parties, primarily engaged in drug development and production	R&D services	2021	10 days	396	0.0%
Total					803,791	100.0%

Note:

- (1) Credit terms are not specified under the relevant contracts.

To the knowledge of our Directors, except for Kelun Group (together with Kelun Medicine & Trade Group) and MSD, none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest customers during the Track Record Period.

COMPETITION

Our industry is highly competitive and subject to rapid and significant change. While we believe that our innovative technology platforms, our drug candidates in both oncology and non-oncology therapeutic areas, and our experienced leadership team provide us with competitive advantages, we face potential competition from many others working to develop therapies targeting the same indications. These include major biopharmaceutical companies, specialty pharmaceutical and biotechnology companies, and academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, please refer the paragraph headed “– Our Pipeline” and “Industry Overview.”

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EMPLOYEES

As of December 31, 2022, we had 1,155 full-time employees, substantially all of whom were based in China. The following table sets forth the details of our employees by function:

Function	Number	% of Total
Research and development*	766	66.3%
Manufacturing and quality control	325	28.1%
Senior management	6	0.5%
General and administrative	58	5.0%
Total	1,155	100.0%

* Including 17 quality control personnel staffed within our research and development team, who were responsible for quality control in our preclinical studies and clinical trials.

We recruit our employees primarily through online platforms, recruiting websites, headhunter referral and job fairs. We conduct induction programs and periodic professional training for all employees.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally determined by their qualifications, performance review, and seniority. We also offer share incentives and promotion opportunities to motivate our employees. See also “Risk Factors – Risks Relating to Our Operations – We may be subject to additional social insurance fund and housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.”

We also enter into separate confidentiality agreements, which contain non-competition clauses, with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business and may be considered possible, directly or indirectly, to compete with us.

As of the Latest Practicable Date, all of our employees were members of our labor union. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our existing insurance policies cover adverse events in our clinical trials, group life insurance, public liability insurance, environmental pollution liability insurance, and general insurance for properties and machinery damage. In line with industry practice in the PRC, we

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have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. We believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in the PRC. See also “Risk Factors – Risks Relating to Our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.”

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We believe our long-term success rests on our ability to make positive impact on the society. As our business continues to grow, we will adhere to our mission to address major medical needs in China and globally, and to bring world-class treatments, and a healthier and happier life, to all patients.

Governance on ESG Matters

We are committed to social responsibilities and consider environmental, social and governance (“**ESG**”) essential to our continuous development. Our Board is responsible for overseeing and guiding our ESG initiatives and setting our ESG strategies and policies. Our Environment, Health and Safety (“**EHS**”) working group is responsible for monitoring the day-to-day practice of ESG-related matters and implementing our ESG policies. We have also set up a dedicated ESG working team, which report to our Board and management team and are responsible for executing the ESG strategies and targets set by the Board.

Our Board is currently in the process of adopting a comprehensive ESG policy (the “**ESG Policy**”) in accordance with the Listing Rules, which will set forth our corporate social responsibility objectives, including (i) the appropriate risk governance on ESG matters; (ii) identification of key stakeholders and the communication channels to engage with them; (iii) our ESG governance structure; (iv) our ESG strategy formation procedures; (v) our ESG risk management and monitoring; and (vi) the identification of key performance indicators and mitigating measures.

We believe our continued growth rests on integrating social values into our business. We are setting up an ESG committee, which will be led and supervised by our management and be responsible for establishing, adopting and reviewing our ESG Policy. The key duties and responsibilities of our ESG committee include:

- keeping abreast of the latest ESG-related laws and regulations, including the applicable sections of the Listing Rules, keeping our management informed of any changes in such laws and regulations, and updating our ESG Policy in accordance with the latest regulatory updates;
- identifying our key stakeholders based on our business operations and understanding such stakeholders’ influences with respect to ESG matters;

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- assessing ESG-related risks on a regular basis to ensure we fulfill our responsibilities with respect to ESG matters;
- ensuring and continuously monitoring the implementation of our ESG Policy and periodically reviewing the effectiveness of our ESG Policy; and
- reporting to our management on an regular basis on the implementation of our ESG Policy and preparing periodic ESG reports.

Environmental Protection

We strive to operate our facilities in a manner that protects the environment. During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with environmental laws and regulations applicable to our operations in all material respects and there had been no material claim or penalty imposed on us as a result of a violation of environmental laws and regulations that would materially and adversely affect our business, financial condition or results of operations. For the year ended December 31, 2021 and 2022, our expenses in relation to environmental compliance matters were RMB668.2 thousand and RMB771.1 thousand, respectively.

Climate-related risks

The environmental and climate-related risks we are exposed to can be divided into two broad categories: physical and transition risks. We define physical risks as risks related to the physical impacts of climate change, consisting of 1) acute physical risks, such as increased severity of typhoon or floods; and 2) chronic physical risks that are affected by long-term changes in climate patterns, such as changes in average annual rainfall or temperature. We define transition risks as the transition from dependence on fossil fuels to a low-carbon economy, which may involve changes in policy, laws, technology markets, as well as social culture, such as possible carbon taxes, compliance disclosures, and increased use of new energy sources across businesses and households. Potential risks to premises, operations, supply chains, transportation needs, and employee safety also impact our finances.

Our ESH working group closely monitors climate change policies to reduce the possible impacts of physical and transition risks. We incorporate environmental risk analysis into the risk assessment process and risk preference setting. If risks and opportunities are deemed material, we incorporate them into our strategic and financial planning processes and take appropriate mitigation measures.

Our business, operations and financial condition had not been materially affected by any climate-related events during the Track Record Period and up to the Latest Practicable Date.

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Energy

We actively explore strategies to reduce energy consumption, primarily electricity consumption. For instance, we actively promote energy conservation and consumption reduction in our daily operations. We encourage the purchase and use of energy-efficient electronic equipment in our office premises, including the choice of lighting and other electrical appliances used. Our employees are reminded to ensure that the air conditioning and other power-consuming equipment at our office premises are switched off when they are not in use.

Water Resources

We focus on water resources issue and actively shoulder the social responsibility of protecting water resources. Municipal water supply networks are the main incoming source of our Company’s water, and we did not encounter major difficulties seeking suitable water sources during the Track Record Period. Since we have not yet started commercial-scale production, our water resources are mainly used for daily use in offices, laboratories and manufacturing facilities to support our in-house research and development activities, and certain construction projects during the Track Record Period.

Emissions

Waste

We have procedures in place for waste management to ensure compliant waste disposal and reduce environmental impact. The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as domestic waste from general office operations). The wastewater and solid waste generated in our in-house research and development process are pretreated by us before being processed by qualified third-party medical waste treatment companies. We use natural gas boilers with low-nitrogen combustion technology, which can significantly reduce emissions of particulates, sulfur dioxide and nitrogen oxide.

Greenhouse gas emission

Our greenhouse gas emissions consist of Scope 1 and Scope 2 emissions. Scope 1 direct emissions include the greenhouse gas emissions from our manufacturing facilities and other stationary combustion sources. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity. In response to the national target of carbon neutrality, we actively focus on reducing the greenhouse gas emissions generated during our operations.

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We rely on various metrics to measure the impact of environmental risks, which are broadly aligned with industry standards. Such metrics include the number of resource consumption, amount of wastewater generated and the amount of hazardous waste generated. We have also set various goals to reduce our environmental impacts, and we continue to take significant steps toward these targets. The following table sets forth our resource use and emission related indicators during the Track Record Period.

	For the years ended	
	December 31,	
	2021	2022
Energy consumption		
Electricity (MWh)	12,281	16,132
Water (tons)	181,073	250,249
Emission		
Exhaust gas (million cubic meters)	37	58
Hazardous waste (tons)	74	104
Greenhouse gas emissions		
(tons of CO ₂ equivalent)	8,694	14,143
– Scope 1 (direct emissions)		
(tons of CO ₂ equivalent)	278	4,585
– Scope 2 (indirect emissions)		
(tons of CO ₂ equivalent)	8,416	9,558

With the expansion of our business and anticipated commercialization of our drug candidates, we expect our resource consumption and emissions to increase. However, we will continue to adopt a wide range of measures, including to strengthen source control, implements cleaner production, rationally utilize resources, conscientiously and responsibly treat laboratory waste and water discharge, and reduce pollution in the whole process. At the same time, we strive to cultivate a corporate culture of environmental protection and work closely with our business partners to build an environment-friendly ecosystem. We are committed to improving the environmental performance of our entire value chain, including office operations, supplier selection, raw material inflow, laboratory experiments, manufacturing process and waste management. In 2023, we aim to control our energy consumption level at approximately 90% to 120% of that recorded in 2022.

Work Safety

We are committed to providing a safe working environment for our employees, as we believe a safe and health workplace is not only important for the well-being of our employees, but also essential to the sustainability of our business. We have implemented rigorous company-wide work safety guidelines and host regular safety training programs to ensure that all of our employees are equipped with the necessary awareness and technical know-how to perform their work in a safe and effective manner. We conduct regular safety inspections for

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our laboratories and manufacturing facilities to assist responsible employees in identifying and rectifying potential health and safety hazards. As an integral part of work safety and quality assurance, we also perform routine maintenance to ensure that all equipment in the laboratories and manufacturing facilities are safe for use, including by identifying and repairing faulty equipment and equipment parts. Since our operations involve the use of hazardous materials, we have implemented safety protocols that set out guidelines on potential safety hazards and procedures for operating in the laboratory and manufacturing facilities, including but not limited to the handling, use, storage, treatment and disposal of hazardous materials, as well as emergency planning and response. During the Track Record Period and up to the Latest Practicable Date, we did not have any major workplace accidents.

Workplace Diversity

Within our organization, we are committed to creating an open and inclusive workplace that promotes equality. We hire employees based on their merits and it is our corporate policy to offer equal opportunities to them regardless of gender, age, race, religion or any other social or personal characteristics. As of December 31, 2022, more than 60% of our total employees were female. We adhere to a fair and transparent employee management system and strive to enhance gender and age diversity of our workforce.

Going forward, intend to actively identify and monitor the actual and potential impact of ESG-related risks on our business, strategy and financial performance and incorporate considerations for ESG issues into our business, strategic and financial planning, in compliance with the recommendation of the Environmental, Social and Governance Reporting Guide in Appendix 27 to the Listing Rules.

PROPERTIES

Owned Properties

Our headquarters are located in Chengdu, Sichuan, China. As of the Latest Practicable Date, we owned land use rights to two parcels of land in the PRC, with an aggregate site area of approximately 132,341.8 m². We hold the valid title for these parcels of land.

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Leased Properties

As of the Latest Practicable Date, we leased 16 properties for production and office use in China, with an aggregate GFA of approximately 36,411.0 m², eight of which were leased from Kelun Group. The following table sets forth the details of our leased properties as of the Latest Practicable Date.

Lessor	Location	GFA (m ²)	Expiration Date	Usage
Kelun Group	Chengdu, Sichuan, China	25,386.61	December 31, 2024	Manufacturing
		207.65	December 31, 2024	Warehouse
		38.76	December 31, 2024	Warehouse
		1,308.4	December 31, 2024	Office
		3,264.72	December 31, 2024	Manufacturing
		3,461.34 in total	December 31, 2024	Residential
		1,455.89 in total	December 31, 2024	Residential
		176.56	December 31, 2024	Residential
Third Party Lessor	Guangzhou, Guandong, China	150.6	July 14, 2023	Office
Third Party Lessor	Hefei, An’hui, China	84.8	March 17, 2024	Office
Third Party Lessor	Xi’an, Shan’xi, China	122.86	July 25, 2024	Office
Third Party Lessor	Shenyang, Liaoning, China	142.72	March 26, 2024	Office
Third Party Lessor	Shanghai, China	61.89	July 8, 2024	Residential
Third Party Lessor	Wuhan, Hubei, China	94.78	April 30, 2026	Office
Third Party Lessor	Guangzhou, Guandong, China	328.60	March 29, 2026	Office
Third Party Lessor	Changsha, Hunan, China	124.77	February 13, 2024	Office

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AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and recognition we received during the Track Record Period.

Award/Recognition	Year Granted	Granting Authority
National Engineering Research Center of Targeted Biologics (生物靶向藥物國家工程研究中心)	2022	NDRC
Innovation and Experiment Center for Postdoctoral Fellows (博士後創新實踐基地)	2021	Human Resources and Social Security Department of Sichuan Province
National High-Tech Enterprise (國家高新技術企業)	2020	Department of Science and Technology of Sichuan Province, Department of Finance of Sichuan Province and Sichuan Provincial Taxation Bureau of the State Administration of Taxation
Engineering Research Center of Sichuan Province (四川省工程研究中心)	2019	Sichuan Provincial Development and Reform Commission
Chengdu New Economy Demonstration Enterprise (成都市新經濟示範企業)	2022	Chengdu New Economic Development Work Leading Group Office
Demonstration Base for Talent Recruitment (成都市引才引智示範基地)	2022	Chengdu Science and Technology Bureau (Foreign Experts Bureau)
The New Economy Gradient Cultivation Enterprises in Chengdu 2021 (2021年成都市新經濟梯度培育入庫企業)	2021	Chengdu New Economic Development and Reform Commission
2020 Rising Enterprise (2020年度雛鷹企業)	2021	Chengdu Wenjiang District New Economy and Technology Bureau

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LICENSES, PERMITS AND APPROVALS

We are subject to regular inspections, examinations and audits, and are required to maintain or renew the necessary permits, licenses and certifications for our business. Our PRC Legal Advisor has advised us that, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations in the PRC. We are planning to renew our Use Permit for Laboratory Animals and High-tech Enterprise Certificate by their expiration date. Our PRC Legal Advisor is of the view that, there are no material foreseeable legal impediments that would prevent us from renewing such licenses, if we comply with all applicable requirements and conditions set forth in relevant laws and regulations. The table below sets forth the relevant details of the material licenses we hold for our operations in China.

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Production License	Our Company	Sichuan Medical Products Administration	May 7, 2022	April 3, 2024
Registration Record of Class II Biosafety Laboratory of Sichuan Province for Infectable Human Pathogenic Microorganisms	Our Company	Chengdu Municipal Health Commission	December 22, 2022	December 22, 2027
Registration Record of Class II Biosafety Laboratory of Sichuan Province for Infectable Human Pathogenic Microorganism	Our Company	Chengdu Municipal Health Commission	December 22, 2022	December 22, 2027
Use Permit for Laboratory Animals	Our Company	Laboratory Animal Committee of Sichuan Province	October 24, 2018	October 24, 2023
High-tech Enterprise Certificate	Our Company	Sichuan Provincial Department of Science, Sichuan Provincial Department of Finance, Sichuan Provincial Taxation Bureau of the State Administration of Taxation	December 3, 2020	December 3, 2023

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License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Pollutant Discharge Permit	Our Company	Chengdu Ecological Environment Bureau	January 10, 2023	January 9, 2028
Consignee and Consignor of Import and Export Goods	Our Company	Chengdu Customs	April 24, 2018	N/A
Record Certificate of Explosives-Prone Hazardous Chemicals Practitioners	Our Company	Wenjiang District Branch of Chengdu Public Security Bureau	October 28, 2021	N/A
Business Registration Certificate	Our Company	Wenjiang Branch of the State Administration of Foreign Exchange	N/A	N/A

LEGAL PROCEEDING AND COMPLIANCE

During the Track Record Period and as of the Latest Practicable Date, we had not been a party to any actual or threatened material legal or administrative proceedings, and our Directors had not been involved in any such proceedings. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. During the Track Record Period and up to the Latest Practicable Date, we had complied in all material respects with the applicable laws and regulations relating to our business operations. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. See “Risk Factors – Risk Relating to Our Operations – We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.”

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global biopharmaceuticals markets, our ability to develop, manufacture and commercialize our drug candidates, and our ability to compete with other biopharmaceutical companies. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit, liquidity, interest rate and currency risks that arise in the normal course of our business. See “Financial Information – Market Risk Disclosure” for a discussion of these market risks.

We have adopted a comprehensive set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors. Our Directors supervise the implementation of our risk management policies.

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To monitor the ongoing implementation of 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:

- Our Directors will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving annual working plan and annual report of our corporate risk management; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Group.
- Our audit department, led by our Risk Prevention and Control Leadership Group (風險防控領導小組), will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) formulating annual working plan and annual report of risk management; (iii) providing guidance on our risk management approach to the relevant departments in our Company and supervising the implementation of our risk management policy by the relevant departments; (iv) reviewing the relevant departments' reporting on key risks and providing feedbacks; and (v) education and training in relation to risk management.
- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework; and (vi) timely report to our audit department and Risk Prevention and Control Leadership Group upon the discovery of material risks.

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.

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Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an independent internal control consultant, or the Internal Control Consultant, to perform certain agreed-upon procedures, or the Internal Control Review, in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group’s entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, contract management, and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in September and October 2022 and follow-up reviews in December 2022. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group’s internal control.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, protection of intellectual property, environmental protection and occupational health and safety. For more information, see “– Intellectual Property” and “– Social, Health, Work Safety and Environmental Matters.” We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports the weakness identified to our management and audit committee and follows up on the rectification actions.
- Our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED]. For more details, please refer to the paragraph headed “Relationship with Our Controlling Shareholders – Corporate Governance Measures” in this document.
- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.
- We have engaged First Shanghai Capital Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [REDACTED] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of funding complies with the section headed “Future Plans and [REDACTED]” in this document after the [REDACTED], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.

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- We plan to engage a PRC law firm to advise us on and keep us abreast with PRC laws and regulations after the [REDACTED]. We will continue to arrange various trainings to be provided by external legal advisers from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations.
- We intend to maintain strict anti-corruption policies among our sales personnel and distributors in our future sales and marketing activities. We will also strive to ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements in the future.

We will conduct periodic review of relevant laws and regulations and amend our internal policies to ensure compliance with the latest applicable laws and regulations.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OVERVIEW

As of the Latest Practicable Date, Kelun Pharmaceutical was directly interested in approximately 59.75% of the total issued Shares of our Company. In addition, our Employee Incentive Platforms, namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide, were directly interested in approximately 15.52% of the total issued Shares of our Company. Kelun Jingchuan, a wholly-owned subsidiary of Kelun Pharmaceutical, is the general partner of each of our Employee Incentive Platforms. As such, Kelun Pharmaceutical was entitled to exercise the voting rights attaching to the Shares held by our Employee Incentive Platforms. Therefore, as of the Latest Practicable Date, Kelun Pharmaceutical was able to exercise approximately 75.27% of the voting rights attaching to the Shares of our Company. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Kelun Pharmaceutical will be entitled to exercise approximately [REDACTED]% voting rights attaching to the Shares directly held by it and those held by our Employee Incentive Platforms. Accordingly, Kelun Pharmaceutical and the Employee Incentive Platforms will continue to be a group of Controlling Shareholders of our Company following the completion of the [REDACTED]. Please see “History and Corporate Structure” for the shareholding and corporate structure of our Group.

Mr. LIU Gexin held approximately 25.77% equity interest in Kelun Pharmaceutical as of March 31, 2023 and is deemed as the actual controller of Kelun Pharmaceutical. According to the Rules Governing the Listing of Shares on the Shenzhen Stock Exchange (《深圳證券交易所股票上市規則》) where Kelun Pharmaceutical is listed, an “actual controller” refers to an individual or entity that can control a company by way of investment relationship, contracts or other arrangements. As the actual controller of Kelun Pharmaceutical, Mr. LIU Gexin is able to control Kelun Pharmaceutical and exert substantial influence over it. Considering Kelun Pharmaceutical itself is able to exercise more than 30% voting power at general meetings of our Company, Mr. LIU Gexin is entitled to, through Kelun Pharmaceutical, indirectly control the exercise of more than 30% of the voting power at general meetings of our Company. Therefore, we also regard Mr. LIU Gexin as our Controlling Shareholder.

Therefore, Kelun Pharmaceutical, the Employee Incentive Platforms and Mr. LIU Gexin are considered as a group of Controlling Shareholders of our Company.

BACKGROUND OF OUR CONTROLLING SHAREHOLDERS

Kelun Pharmaceutical (stock code: 002422) was listed on the Shenzhen Stock Exchange in June 2010. The Remaining Kelun Group is a global leading IV (intravenous) fluids solution products and antibiotics intermediates manufacturer. Pursuant to Kelun Pharmaceutical’s A-share annual report of 2022 published on the Shenzhen Stock Exchange, under the PRC GAAP, its total revenue and profit attributable to shareholders reached approximately RMB18,912.65 million and RMB1,708.70 million respectively for the year ended December 31, 2022. Kelun Group is a highly specialized pharmaceutical group with over 60 subsidiaries and branches in China and overseas, including, among others, Kelun Research Institute, which primarily focuses on research and development of generic drugs.

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For Mr. LIU Gexin’s background, please refer to “Directors, Supervisors and Senior Management – Board of Directors – Chairman of the Board and Non-executive Director” in this document. Mr. LIU Gexin is the actual controller of Kelun Pharmaceutical. Other than his voting interest in Kelun Pharmaceutical, Mr. LIU Gexin did not hold or was otherwise interested in the share capital of our Company, nor had he been involved in the day-to-day management or operations of our Group as a non-executive Director and Chairman of the Board. Mr. LIU Gexin was of the view that our Company has been amply and soundly managed by our Board and senior management and hence did not take on any executive role in our Company.

SPIN-OFF

Kelun Pharmaceutical, our Controlling Shareholder, is a company listed in the PRC. The [REDACTED] of our Company constitutes a spin-off from a domestic listed company (the “**Spin-Off**”) as defined under the Spin-off Rules. The Spin-Off has been approved by the shareholders of Kelun Pharmaceutical at an extraordinary general meeting held on January 30, 2023. Kelun Pharmaceutical filed the relevant announcements related to the Spin-Off with the Shenzhen Stock Exchange on January 14, 2023.

DELINEATION OF BUSINESS BETWEEN US AND OUR CONTROLLING SHAREHOLDER

We were an internal platform of Kelun Group committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally. We were founded by Kelun Pharmaceutical and Employee Incentive Platforms as a joint stock company limited by shares in 2016. The Remaining Kelun Group, however, is an integrated research-driven and market-oriented pharmaceutical company primarily focusing on: (i) manufacturing of IV (intravenous) fluids solution products and antibiotics intermediates (the “**Manufacturing Business**”); and (ii) research and development of generic drugs, which are mainly carried out through Kelun Research Institute (the “**Generic Drug R&D Business**”).

Delineation with the Manufacturing Business

The Manufacturing Business mainly focuses on IV fluids solution products and antibiotics intermediates that have been commercialized and widely used in clinical treatment. In contrast, the overall business of our Group is at the pre-commercialization stage with R&D, manufacturing and commercialization of novel drugs to address medical needs. As such, we believe that our business and the Manufacturing Business are explicitly differentiated in nature.

Delineation with the Generic Drug R&D Business

The Generic Drug R&D Business mainly focuses on research, development and commercialization of generic drugs. In contrast, our Group mainly focuses on the discovery, R&D and commercialization of novel drugs. In general, novel drugs and generic drugs are two different classes of drugs that are generally used to treat different stages of patients with a

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given disease, based on various factors including disease subtype, disease progression (i.e., treatment line) and the patient’s medical history. Therefore, novel drugs and generic drugs are generally not in competition with each other, as confirmed by Frost & Sullivan. The main differences between novel drugs and generic drugs in the Chinese market are generally the following:

	Novel Drugs	Generic Drugs
Nature	Pharmaceutical drug with independent property rights. Comparing against generic drug, it emphasizes on novel chemical structure or novel treatment method with the aim of addressing medical needs.	Pharmaceutical drug containing the same chemical substances as a drug that was originally protected by chemical patents (i.e., brand-name drug). A generic drug has the same active pharmaceutical ingredients as the brand-name drug and is allowed for sale after the patents of the brand-name drug expire. As such, a generic drug is identical to or within an acceptable bioequivalent range of the brand-name drug with respect to pharmacokinetic and pharmacodynamics properties.
R&D Model and Cycle	Development of a drug that contains active ingredient(s) not previously approved in a drug by a regulatory authority and enjoys proprietary barriers to entry, including regulatory or patent-derived market exclusivity.	Development of a drug identical to, or within an acceptable bioequivalent range of, an already marketed brand-name drug in active ingredients, therapeutic effect, safety, and intended use, among other criteria.
Time to Market	Longer than generic drugs primarily attributable to the preclinical studies and clinical trials that are required of the novel drugs to demonstrate safety and effectiveness. According to Frost & Sullivan, it normally takes approximately ten to 15 years for a novel drug to complete R&D cycle.	Relative shorter than novel drugs primarily because generic drug applicants do not have to repeat the preclinical studies and clinical trials required of their brand-name counterparts. According to Frost & Sullivan, it normally only takes approximately 3 years for a generic drug to complete its R&D cycle.

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	Novel Drugs	Generic Drugs
R&D Cost	Novel drugs have to go through expensive animal and clinical studies to prove their safety and efficacy. According to Frost & Sullivan, the R&D cost of a novel drug normally amounts to US\$500 million to US\$1 billion.	Generic drugs use the same active ingredients that the brand-name drugs carried out testing for, so they don’t have to conduct the same testing, which benefits generic drugs from a reduction in upfront research costs. According to Frost & Sullivan, the R&D cost of a generic drug normally amounts to US\$1 million to US\$3 million.
Treatment Costs	Typically maintained at a high level before patent expiration.	Typically sold at substantial discounts, due to significant reduction in upfront research costs.
Clinical Needs	Addressing medical needs that cannot be met by generic drugs through offering new therapeutic options to patients previously without available or effective treatments.	Providing affordable substitutes that work in the same way and offer the same clinical benefit as the marketed brand-name drug.
Sales and Promotion Channel	Unlike generic drugs whose sales and promotion channel in China may be constrained if not being selected through collective pharmaceutical procurement, there are no similar restrictions on the sales and promotion channel for novel drugs in China. Developers of novel drugs face a broader target market and can deploy more diversified marketing and sales strategies to promote their novel drugs.	In China, the primary and most important sales channel of generic drugs is through collective pharmaceutical procurement organized by government. Physicians at public hospitals usually only prescribe generic drugs that have been selected by collective pharmaceutical procurement. Failure to be selected through collective pharmaceutical procurement may result in significant constraints on the sales and promotion channel of such generic drug.

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	Novel Drugs	Generic Drugs
Physician Prescribing Behavior	Given the innovative nature of novel drugs, there is no similar labeling requirement which applies to generic drugs. As such, physician prescribing behavior in respect of novel drugs is usually influenced by education conducted by novel drug developers.	Physicians usually prescribe generic drugs by strictly following generic drug labeling, which is the same as the last approved reference listed drug labeling except for permissible differences (e.g., manufacturer/packer/distributor information package size, etc.)
Direct Competitors	Approved drugs or drug candidates in the same class that treat the same indications.	When multiple generic drugs are approved based on the same brand-name drug, more competition exists in the marketplace.

Although certain drugs of the Remaining Kelun Group and our Group are designed for the same broad disease types, their drug modalities, targets, mechanism of action, indications and treatment lines are different. In practice, doctors determine the type and order of therapies given to a patient generally based on established treatment guidelines, recently published clinical trial results, progression of disease and patient’s individual situation. The initial therapy used, for example, is referred to as first-line (1L) treatment, followed by second- and later-line (2L+) treatments and so on, after an earlier-line treatment has failed. Certain drugs of the Remaining Kelun Group and our Group designed for the same broad disease types are positioned for different lines of treatment to target the various subpopulations of patients. As such, these drugs are not interchangeable and cannot be replaced by each other. Our Company and our Controlling Shareholders consider that these drugs will not affect the business delineation or give rise to material competition between our Group and the Remaining Kelun Group because of the following:

Oncology Drugs

Cancer treatments have evolved rapidly over the past few decades. The landscape of cancer treatments has progressed from surgery and indiscriminate cytotoxic treatments, such as radiotherapy and chemotherapy, to more innovative modalities such as targeted therapies and immunotherapies, represented by antibody-based drugs, including mAbs, bsAbs and ADCs. For an overview of the oncology drug market, see “Industry Overview – The Oncology Drug Market.”

The Remaining Kelun Group specializes in the development of generic drugs as affordable substitutes to marketed brand-name drugs, the latter having existed in the market for a number of years. In contrast, our Group is dedicated to the development of novel drugs representing some of the most cutting-edge treatment modalities in China and globally. For

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example, our Core Products, SKB264 and A166, are ADC candidates developed based on our proprietary technologies to selectively target and kill tumor cells. These types of drugs are differentiated from that of traditional cancer treatments like chemotherapy due to fundamentally different treatment philosophies. For example, two of the Remaining Kelun Group’s generic drug products are chemotherapy drugs, which are a typical modality of generic drugs that kill both tumor cells and normal cells indiscriminately, leading to serious safety issues. Chemotherapy drugs therefore have mechanisms of action and efficacy and safety profiles differentiated from those of ADCs. As such, the generic chemotherapy drugs developed by the Remaining Kelun Group are different in nature from, and hence generally not in competition with, the ADCs and other targeted therapies developed by our Group.

Moreover, the generic targeted therapies developed by the Remaining Kelun Group and the innovative targeted therapies developed by our Group are directed toward different molecular targets. Driven by the shifting paradigm towards precision oncology, cancer therapies are developed with the recognition that tumors are highly heterogenic in nature and there is no one-size-fits-all approach to cancer care. Due to the difference in tumor profiles between patients, targeted therapies directed toward a particular target are typically only effective in a specific subset of cancer patients. For example, small molecule inhibitor directed toward PARP may only be effective for platinum-sensitive recurrent OC patients but not for platinum-resistant recurrent OC patients. Therefore, targeted therapies directed toward different molecular targets are generally not in competition with each other. For more details on ADCs, their innovative features and competitive landscape, see “Industry Overview – The Antibody-based Drug Market – The ADC Market.”

(i) Breast Cancer (BC)

	Our Group		Remaining Kelun Group	
	SKB264	A166	Paclitaxel for injection (Albumin Bound) (注射用紫杉醇(白蛋白结合型))	Palbociclib (哌柏西利)
Drug Modality	ADC	ADC	Chemo	Small molecule kinase inhibitor
Target (if any)	TROP2	HER2	N/A	CDK4/6
Mechanism of Action	SKB264 is a novel TROP2 ADC that elicits both targeted killing in TROP2-expressing tumor cells and bystander killing in TROP2-negative tumor cells, which helps overcome heterogeneity in tumors where there is uneven expression of TROP2.	A166 is a differentiated HER2 ADC that potentially exerts strong anti-tumor activity via HER2-targeted cell killing, inhibition of HER2 signaling and ADCC.	Paclitaxel (albumin-bound) is a cytotoxic drug that disrupts microtubule inside the cell, thereby causing cell death.	Palbociclib is a selective CDK4/6 inhibitor that interrupts the process through which tumor cells divide and multiply.

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	Our Group		Remaining Kelun Group	
	SKB264	A166	Paclitaxel for injection (Albumin Bound) (注射用紫杉醇(白蛋白結合型))	Palbociclib (哌柏西利)
Indication(s) and Treatment Lines	<p><i>Advanced TNBC:</i></p> <ul style="list-style-type: none"> • third-line and beyond (3L+) • first-line (1L) combo with PD-L1 mAb <p><i>HR+/HER2- BC: second-line and beyond (2L+)</i></p>	<p><i>Advanced HER2+BC that fails HER2 mAb treatment: third-line and beyond (3L+)</i></p>	<p><i>Metastatic BC that failed combination chemotherapy or recurrent BC within six months of adjuvant chemotherapy (except for contraindication, prior treatment should include anthracycline-based chemotherapy): second-line and beyond</i></p>	<p><i>Advanced HR+/HER2- BC: first-line (1L) combo with aromatase inhibitor</i></p>

Paclitaxel (albumin bound) is a chemotherapy drug, which belongs to an entirely different class of cancer treatment compared to ADC drugs like SKB264 and A166. These two classes of cancer treatments differ in terms of drug modality, mechanisms of action and efficacy and safety profiles. Due to these differences, paclitaxel (albumin bound) would be used to treat a different population of cancer patients from that of SKB264 and A166 (i.e., different treatment lines and treatment history). Therefore, SKB264 and A166 and the Remaining Kelun Group’s paclitaxel (albumin bound) are not substitutable for, nor in competition with, each other.

Palbociclib is a type of targeted therapy that targets CDK4/6 proteins to interrupt the process through which tumor cells divide and multiply. The molecular target of palbociclib (CDK4/6) is different from that of SKB264 (TROP2) and A166 (HER2). Due to their differentiated molecular targets and hence mechanisms of action, palbociclib would be used to treat a different population of cancer patients from that of SKB264 (i.e., different treatment lines) and that of A166 (i.e., different molecular subtype of cancer). Therefore, SKB264 and A166 and the Remaining Kelun Group’s palbociclib are not substitutable for, nor in competition with, each other.

(ii) Lung Cancer (LC)

	Our Group		Remaining Kelun Group			
	SKB264	A400	Pemetrexed disodium powder for injection (培美曲塞二鈉粉針)	Gefitinib (吉非替尼)	Erlotinib (厄洛替尼)	Afatinib (阿法替尼)
Drug Modality	ADC	Small molecule tyrosine kinase inhibitor (“TKI”)	Chemo		Small molecule TKI	
Target (if any)	TROP2	RET	N/A		EGFR	

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

	Our Group		Remaining Kelun Group			
	SKB264	A400	Pemetrexed disodium powder for injection (培美曲塞二鈉粉針)	Gefitinib (吉非替尼)	Erlotinib (厄洛替尼)	Afatinib (阿法替尼)
Mechanism of Action	SKB264 is a novel TROP2 ADC that elicits both targeted killing in TROP2-expressing tumor cells and bystander killing in TROP2-negative tumor cells, which helps overcome heterogeneity in tumors where there is uneven expression of TROP2.	A400 is a highly selective and potent small molecule RET inhibitor that selectively inhibits oncogenic RET signaling in RET+ tumor cells.	Pemetrexed is a multi-targeted anti-cancer antifolate containing the pyridopyrimidine-based nucleus that exerts its antineoplastic activity by disrupting folate-dependent metabolic process essential for cell replication.	Gefitinib, erlotinib and afatinib are EGFR TKIs that disrupt oncogenic EGFR signaling in EGFR-mutant tumor cells.		
Indication(s) and Treatment Lines	<p><i>Driver mutation-negative advanced NSCLC and driver mutation-positive advanced NSCLC, including EGFR-mutant NSCLC that fails EGFR TKI treatments: second line and beyond (2L+)</i></p> <p><i>Drive mutation-negative advanced NSCLC: first line (1L) in combination with PD-L1 mAb</i></p> <p><i>Advanced SCLC: second line and beyond (2L+)</i></p>		<p><i>Advanced RET+ NSCLC: first line and beyond (1L+)</i></p>	<p><i>Advanced NSCLC with non-squamous histology: first line and beyond (1L+)</i></p>	<p><i>Advanced EGFR-mutant NSCLC: first line and beyond (1L+)</i></p>	

Pemetrexed is a chemotherapy drug that indiscriminately kills both cancer cells and normal cells, which frequently leads to safety and toxicity issues in patients. Conversely, both SKB264 and A400 are two types of targeted therapy designed to selectively target cancer cells that express a specific protein. Because of their differentiated drug modalities and hence mechanisms of action and efficacy and safety profiles, pemetrexed would be used to treat a different population of cancer patients from that of SKB264 (i.e., different cancer cell histology, tumor cell anatomy under the microscope that reflects the underlying molecular processes and disease progression, and different treatment lines) and that of A400 (i.e., different cancer molecular subtypes and cell histology). Therefore, SKB264 and A400 are not substitutable for, nor in competition with, the Remaining Kelun Group’s pemetrexed.

Although EGFR TKIs gefitinib, erlotinib and afatinib are also targeted therapies, their drug modality is different from that of SKB264, and their molecular target (EGFR) is different from that of SKB264 (TROP2) and A400 (RET), which leads to a completely different mechanism of action and therapeutic profile. As a result, gefitinib, erlotinib and afatinib would be used to treat a different population of cancer patients from that of SKB264 (i.e., different lung cancer subtypes and/or different treatment lines) and that of A400 (i.e., different cancer molecular subtypes). Therefore, our SKB264 and A400 and the remaining Kelun Group’s gefitinib, erlotinib and afatinib are not substitutable for, nor in competition with, each other.

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(iii) Colorectal Cancer (CRC)

	A166	Our Group A140	Remaining Kelun Group Regorafenib (瑞戈非尼)
Drug Modality	ADC	mAb	Small molecule multi-kinase inhibitor
Target (if any)	HER2	EGFR	multiple angiogenic, stromal and oncogenic RTKs
Mechanism of Action	A166 is a differentiated HER2 ADC for treating HER2+ or HER2-mutant solid tumors. It potentially enables strong anti-tumor activity via HER2-targeted cell killing, inhibition of HER2 signaling and ADCC.	A140 is an EGFR mAb that exerts anti-tumor effects primarily via the interruption of oncogenic EGFR signaling in tumor cells that overexpress EGFR.	Regorafenib is a multi-kinase inhibitor with a triple mechanism of action against RTKs involved in the regulation of angiogenesis, cell proliferation and tumor stroma.
Indication(s) and Treatment Lines	<i>Advanced HER2+ CRC with wild-type RAS/BRAF proteins, for whom regorafenib has demonstrated limited efficacy with an ORR of about 5% in clinical trials: third line and beyond (3L+)</i>	<i>RAS wild-type metastatic CRC (mCRC): first line (1L)</i>	<i>mCRC that fails fluorouracil, oxaliplatin and irinotecan-based chemotherapy, and mCRC that fails or are not suitable for anti-VEGF therapy or anti-EGFR therapy: third line and beyond (3L+)</i>

Regorafenib is a type of targeted therapy with a different molecular target (multiple receptor tyrosine kinases) from that of A166 (HER2) and A140 (EGFR), which results in a completely different mechanism of action and therapeutic profile from that of A166 and A140. As a result, regorafenib would be used to treat a different population of cancer patients from that of A166 (i.e., different cancer molecular subtypes and medical history) and that of A140 (i.e., different treatment lines). Therefore, A166 and A140 are not substitutable for, nor in competition with, the remaining Kelun Group’s regorafenib.

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(iv) *Ovarian Cancer (OC)*

	Our Group SKB264	Remaining Kelun Group Olaparib (奥拉帕利)
Drug Modality	ADC	Small molecule inhibitor
Target (if any)	TROP2	PARPs
Mechanism of Action	SKB264 is a novel TROP2 ADC that elicits both targeted killing in TROP2-expressing tumor cells and bystander killing in TROP2-negative tumor cells, which helps overcome heterogeneity in tumors where there is uneven expression of TROP2.	Olaparib is a small molecule PARP inhibitor that suppresses the DNA repair pathway and causes cytotoxic DNA damage to tumor cells.
Indication(s) and Treatment Lines	<i>Platinum-resistant recurrent OC: second line and beyond (2L+)</i>	<i>Platinum-sensitive recurrent OC: second line and beyond (2L+)</i>
	<i>Note: Platinum-resistant recurrent OC refers to OC that recurs less than six months after completing 1L platinum-based chemotherapy</i>	<i>Note: platinum-sensitive recurrent OC refers to OC that recurs more than six months after completing 1L platinum-based chemotherapy</i>
		<i>OC with germline BRCA1/2 mutation: first line (1L)</i>
		<i>Advanced BRCA1/2-mutated OC after 1L chemotherapy, platinum-sensitive recurrent OC after chemotherapy: adjuvant treatment</i>

Olaparib is a type of targeted therapy with a different drug modality and molecular target from that of SKB264, which leads to a completely different mechanism of action and therapeutic profile. As a result, Olaparib would be used to treat a different population of cancer patients from that of SKB264 (i.e., different platinum sensitivity, cancer molecular subtypes and treatment lines). Therefore, our SKB264 is not substitutable for, nor in competition with, the remaining Kelun Group’s olaparib.

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(v) *Thyroid Cancer (TC)*

	Our Group	Remaining Kelun Group
	A400	Sorafenib tosylate (甲苯磺酸索拉非尼)
Drug Modality	Small molecule TKI	Small molecule multi-kinase inhibitor
Target (if any)	RET	Multiple protein kinases
Mechanism of Action	A400 is a highly selective and potent small molecule RET inhibitor that selectively inhibits oncogenic RET signaling in RET+ tumor cells.	Sorafenib is a multi-kinase inhibitor that suppresses many protein kinases and induces autophagy that inhibit tumor growth.
Indication(s) and Treatment Lines	<i>Advanced RET+ MTC</i> : first line and beyond (1L+)	<i>Advanced progressive radioactive iodine-refractory differentiated TC</i> : second line (2L)

Sorafenib is a type of targeted therapy with a different molecular target from that of A400, which leads to a completely different mechanism of action and therapeutic profile. As a result, sorafenib would be used to treat a different cancer patient population from that of A400 (i.e., different cancer molecular subtypes, cell histology, treatment history and treatment lines). Therefore, our A400 is not substitutable for, nor in competition with, the remaining Kelun Group’s sorafenib.

Non-oncology Drug

Rheumatoid Arthritis (RA)

	Our Group	Remaining Kelun Group	
	A223	Tofacitinib citrate (枸橼酸托法替布)	Celecoxib (塞來昔布)
Drug Modality	Small molecule inhibitor	Small molecule inhibitor	Small molecule inhibitor
Target (if any)	JAK1/2	preferentially JAK1/2/3	COX-2

Different JAKs have different cell type-specific expression patterns and are associated with different cytokine receptors, thus the blockade of different JAKs may lead to different biological outcomes. JAK1 and JAK2 are broadly expressed in most types of cells and tissues, while JAK3 is primarily expressed in bone marrow cells, thymocytes, NK cells, and activated B and T lymphocytes. Therefore treatment with tofacitinib, but not A223, would have a greater inhibitory effect on the functions of the aforementioned immune cell types.

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	Our Group	Remaining Kelun Group	
		Tofacitinib citrate (枸橼酸托法替布)	Celecoxib (塞來昔布)
A223			
Mechanism of Action	A223 is potentially one of the first domestically developed small molecule inhibitors that inhibit JAK1 and JAK2, thereby potentially suppressing cytokine-mediated inflammation and preventing the progression of joint damage in RA.	Tofacitinib preferentially inhibits JAK1, JAK2 and JAK3, thereby potentially suppressing cytokine-mediated inflammation and preventing the progression of joint damage in RA	Celecoxib inhibits COX-2-mediated prostaglandin synthesis to potentially reduce sensitivity to pain and joint swelling.
Indication(s)	<i>Adult patients with moderate to severe RA</i> <i>Adult patients with alopecia areata</i>	<i>Adult patients with moderate-to-severe RA who have had an inadequate response or intolerance to one or more types of TNF inhibitors</i> <i>Adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF inhibitors</i>	It only provides symptomatic relief via the reduction of pain sensitivity and joint swelling, but it does not slow or prevent disease progression.
Drug half-life	Expected half-life of 16 to 18 hours, which are considerably longer than that of tofacitinib. As such, A223 can be dosed much less frequently than tofacitinib.	3 hours	11 hours

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A223 and tofacitinib are JAK inhibitors with different selectivity towards the four JAK enzymes, which have distinct biological functions. A223 selectively inhibits JAK1 and JAK2, while tofacitinib inhibits all four JAKs. Due to the difference in JAK selectivity, A223 has different pharmacological properties, efficacy and safety profiles as well as dosing regimen from that of tofacitinib. Therefore, A223 and tofacitinib would be used to treat distinct diseases (i.e., AA for A223, ankylosing spondylitis for tofacitinib). Moreover, even though both A223 and tofacitinib both target RA, their effectiveness and safety for RA vary according to each patient’s treatment history, susceptibility to different adverse drug reactions and potential drug-drug interactions. For example, baricitinib (also a JAK1/2 inhibitor) has been shown to be more effective than tofacitinib in patients who have previously received multiple biologic disease-modifying rheumatic drugs. As such, A223 and the Remaining Kelun Group’s tofacitinib are not substitutable for, nor in competition with, each other on the same patient.

On the basis of the above, each of our Controlling Shareholders and our Company believes that there is a clear business delineation of business between our Group and the Remaining Kelun Group, and our Directors are of the view that the business of Remaining Kelun Group does not compete, and is unlikely to compete, directly or indirectly, with our Group’s business. Our Controlling Shareholders further confirmed that, as of the Latest Practicable Date, save as disclosed in this section, they do not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules.

DEED OF NON-COMPETITION

In order to avoid potential competition between the Remaining Kelun Group and our Group and protect the interests of the shareholders of the Remaining Kelun Group and our Shareholders, each of our Controlling Shareholders, namely Kelun Pharmaceutical and Mr. LIU Gexin, has entered into a deed of non-competition (referred to as “**Kelun Pharmaceutical’s Deed of Non-competition**” and “**Mr. LIU’s Deed of Non-competition**”, collectively referred to as the “**Deed of Non-Competition**”) with the Company.

Pursuant to Kelun Pharmaceutical’s Deed of Non-competition, the Remaining Kelun Group has made the following confirmations and undertakings:

- (a) it is not directly or indirectly engaged in any business which is the same or similar to, or constitutes direct or indirect competition with, the principal business or principal products of our Group;

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- (b) during the period of being a Controlling Shareholder of our Company, it will not, directly or indirectly, in any way (including but not limited to new establishment, acquisition or merger of companies or other economic organizations within or outside the PRC) participate in any business which is the same or similar to, or has direct or indirect competition with, the principal business or principal products of our Group;
- (c) if it obtains any business opportunities from the market in the future that constitute substantial competition with the principal business of our Group, under the same conditions of possessing relevant development qualifications, tender conditions and obtaining third-party consent (if required), it will use its best endeavours to facilitate our Group to secure such business opportunities;
- (d) it will not use the information obtained or known from our Group to assist any third party to engage in business that involves substantial competition with the business conducted by our Group;
- (e) it shall procure other enterprises, organizations or institutions controlled by it to comply with Kelun Pharmaceutical's Deed of Non-Competition; and
- (f) it agrees to indemnify our Company for any losses or expenses suffered or incurred as a result of any breach of any terms of Kelun Pharmaceutical's Deed of Non-competition by the Remaining Kelun Group.

Pursuant to Mr. LIU's Deed of Non-competition, Mr. LIU Gexin has made the following confirmations and undertakings:

- (a) the enterprises, organizations or institutions controlled by him will not directly or indirectly engage in any business which is the same or similar to, or constitutes competition with, the principal business or principal products of our Group;
- (b) during the period of being a Controlling Shareholder of our Company, the enterprises, organizations or institutions controlled by him will not directly or indirectly, in any way (including but not limited to new establishment, acquisition or merger of companies or other economic organizations within or outside the PRC) participate in any business which is the same or similar to, or has direct or indirect competition with, the principal business or principal products of our Group;
- (c) if our Company explores new areas of business in the future which causes the business conducted by the enterprises, organizations or institutions controlled by him to compete with our Company, the enterprises, organizations or institutions controlled by him shall cease engaging in such business, or our Company shall have

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the pre-emptive right to acquire the underlying assets or equity interests of such business under the same conditions, or the underlying assets or equity interests of such business shall be transferred to unrelated third parties based on the principles of fairness and impartiality;

- (d) he will procure other enterprises, organizations or institutions controlled by him to comply with Mr. LIU’s Deed of Non-competition;
- (e) he will not provide proprietary technology or trade secrets such as sales channels and customer information to other companies, enterprises or other institutions, organizations or individuals whose businesses are the same or similar to, or compete in any respect with our Company; and
- (f) he agrees to indemnify our Company for any losses or expenses suffered or incurred by our Company as a result of any breach of any terms of Mr. LIU’s Deed of Non-competition.

The overall business of our Group is at the pre-commercialization stage with R&D, manufacturing and commercialization of novel drugs to address medical needs. By contrast, the Remaining Kelun Group is an integrated pharmaceutical company primarily focusing on the Manufacturing Business and Generic Drug R&D Business. As such, “any business which is the same or similar to, or constitutes direct or indirect competition with, the principal business or principal products of our Group” referred to in the Deed of Non-competition particularly refers to the R&D, manufacturing and commercialization of novel drugs.

As further elaborated below, our independent non-executive Directors shall review, at least on an annual basis, the compliance with the Deed of Non-competition by our Controlling Shareholders. Each of our Controlling Shareholders shall and shall procure his/its relevant close associates to provide all information necessary for the annual review by our independent non-executive Directors for the enforcement of the Deed of Non-competition. Given the fundamental differences of the business focus of the Group and our Controlling Shareholders, which can be differentiated by, among others, nature of drugs, R&D model and cycle, time to market, clinical needs, and sales and marketing channel, it is relatively straightforward and easy to assess whether the Controlling Shareholders have complied with the Deed of Non-competition in reality. As such, the Company believes that the Deed of Non-competition could be effectively implemented to achieve its intended purpose.

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If any new business investment or other business opportunity that constitute substantial competition with the principal business of our Group (the “**Competing Business Opportunity**”) is identified by or made available to our Controlling Shareholders or their close associates, they will, and will procure that their close associates shall, refer such Competing Business Opportunity to our Company on a timely basis and refer the Competing Business Opportunity to our Company by giving written notice (the “**Offer Notice**”) to our Company of such Competing Business Opportunity within 30 business days of identifying the target company (if relevant) and the nature of the Competing Business Opportunity, the investment or acquisition costs and all other details reasonably necessary for our Company to consider whether to pursue such Competing Business Opportunity.

Upon receiving the Offer Notice, our Company shall seek approval from our Board or a board committee (in each case comprising only disinterested Directors) which has no interest in the Competing Business Opportunity (the “**Disinterested Board**”) as to whether to pursue or decline the Competing Business Opportunity (any Director who has actual or potential interest in the Competing Business Opportunity shall abstain from attending (unless their attendance is specifically requested by the Disinterested Board) and voting at, and shall not be counted in the quorum for, any meeting convened to consider such Competing Business Opportunity).

The Disinterested Board shall consider the financial impact of pursuing the Competing Business Opportunity offered, whether the nature of the Competing Business Opportunity is consistent with our Group’s strategies and development plans and the general market conditions of our business. If appropriate, the Disinterested Board may appoint independent financial advisors and legal advisors to assist in the decision-making process in relation to such Competing Business Opportunity. The Disinterested Board shall, within 30 business days of receipt of the Offer Notice, inform our Controlling Shareholders in writing, on behalf of our Company, its decision whether to pursue or decline the Competing Business Opportunity.

Our Controlling Shareholders shall be entitled but not obliged to pursue such Competing Business Opportunity if they have received a notice from the Disinterested Board declining such Competing Business Opportunity or if the Disinterested Board failed to respond within such 30 business days’ period mentioned above. If there is any material change in the nature, terms or conditions of such Competing Business Opportunity pursued by our Controlling Shareholders, they will refer such revised Competing Business Opportunity to our Company as if it were a new Competing Business Opportunity.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

INDEPENDENCE OF OUR GROUP FROM OUR CONTROLLING SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independently from our Controlling Shareholders and their close associates after the [REDACTED].

Management Independence

Our business is managed and conducted by our Board and senior management. Upon [REDACTED], our Board will consist of eleven Directors comprising two executive Directors, five non-executive Directors and four independent non-executive Directors. For more information, please see “Directors, Supervisors and Senior Management” in this document. Out of the eleven Directors, three non-executive Directors currently hold positions in the Remaining Kelun Group, details of which are set out as below:

Name	Positions, roles and responsibilities in the Controlling Shareholder as of the Latest Practicable Date	Positions, roles and responsibilities in our Company
Mr. LIU Gexin (劉革新)	Chairman and secretary of the Party Committee of Kelun Pharmaceutical and director of various subsidiaries of Kelun Group	Chairman of the Board and non-executive Director, responsible for overseeing the management and strategic development of the Group
Mr. LIU Sichuan (劉思川)	Director and general manager of Kelun Pharmaceutical and director and/or manager of various subsidiaries of Kelun Group	Non-executive Director, responsible for overseeing the management and strategic development of the Group
Mr. FENG Hao (馮昊)	Deputy general manager and secretary to the board of directors of Kelun Pharmaceutical	Non-executive Director, responsible for overseeing the management and strategic development of the Group

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Our Directors are of the view that the Board and the senior management of our Company are able to function independently of the Remaining Kelun Group for the following reasons:

- (a) our executive Directors, who are responsible for the day-to-day management of the Group’s business, do not have any ongoing roles in the Remaining Kelun Group;
- (b) save as disclosed above, none of our other Directors has any ongoing role with the Remaining Kelun Group;
- (c) a majority of the members of the Board, including the executive Directors and all the independent non-executive Directors, will be independent of the Remaining Kelun Group;
- (d) none of the members of our senior management have any ongoing managerial role with the Remaining Kelun Group;
- (e) should there be a conflict of interest or a connected transaction between our Group (on one hand) and members of the Remaining Kelun Group (on the other hand), the relevant overlapping directors will abstain from voting on, and will not be counted in the quorum for, the relevant board resolution(s) of our Company and relevant member(s) of the Remaining Kelun Group; and
- (f) we will adopt corporate governance policies, including but not limited to, rules relating to the procedure for board meetings and decision-making protocols on connected transactions, setting out circumstances that require the relevant common directors to abstain from voting on, and not to be counted in the quorum for, the relevant board resolutions.

Operational Independence

We are an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally. Over the years, we have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization. Our Group is able to operate without reliance on the Remaining Kelun Group on the following basis:

Research and development

Our Group has an R&D center independent from the R&D centers of the Remaining Kelun Group. As of December 31, 2022, our R&D team comprised over 760 members, all of whom are full-time employees of our Group not holding any position in the Remaining Kelun Group. With such independent R&D center, and experienced and independent R&D team, our

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Group has the requisite resources to carry on the R&D process independently. Currently, all of our fundamental and core on-going R&D activities, including preclinical studies and clinical trials are conducted independently by our R&D team without reliance on our Controlling Shareholders.

During the Track Record Period and in the ordinary and usual course of business, we have engaged certain subsidiaries of the Remaining Kelun Group to provide auxiliary R&D services (the “**Auxiliary R&D Procurement Services**”), which include process development and optimization, sample purification, crystallization screening, GMP batch release testing and packing material release testing. Following the [REDACTED], we expect to continue engaging the Remaining Kelun Group to provide these Auxiliary R&D Procurement Services on an arm’s length basis and on normal commercial terms. Such transactions will constitute continuing connected transactions of our Company upon completion of the [REDACTED]. For further details, see “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement and Provision of Auxiliary R&D Services.”

Our Company is of the view that such Auxiliary R&D Procurement Services provided by the Remaining Kelun Group will not affect our ability to operate independently from the Remaining Kelun Group for the following reasons:

- (a) we are able to function independently of the Remaining Kelun Group in every aspect of our business, including among other things, R&D and commercialization. Particularly, we are not relying on the Remaining Kelun Group in relation to conducting fundamental and core R&D and clinical trial for our products, since we have our own R&D team and are able to take lead in all important and core stages of the clinical trial process.

The Auxiliary R&D Procurement Services provided by the Remaining Kelun Group are not core to our R&D activities. It is common for pre-profit biopharmaceutical companies like us to outsource these Auxiliary R&D Procurement Services to third parties so the pre-profit biopharmaceutical companies can concentrate on core R&D of their drug candidates. According to Frost & Sullivan, the Auxiliary R&D Procurement Services we procure from the Remaining Kelun Group are widely available in the market from contract development and manufacturing organizations in the PRC, and the terms are comparable to those set out in the Auxiliary R&D Services Framework Agreement.

- (b) we are under no obligation to enter into such agreement with the Remaining Kelun Group. Prior to engaging the relevant members of the Remaining Kelun Group as a service provider for Auxiliary R&D Procurement Services, our Group would approach and engage in discussion and negotiations with other independent service providers before making the decision.

We engaged the Remaining Kelun Group to provide Auxiliary R&D Procurement Services to us because (i) the Remaining Kelun Group has competent and reliable expertise in providing Auxiliary R&D Procurement Services and can provide such services at arm’s length and with good quality; and (ii) we have been cooperating with the Remaining Kelun Group for Auxiliary R&D Procurement Services for

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anumber of years and the Remaining Kelun Group understands our quality requirement for these services quite well. Continuous procuring such services from the Remaining Kelun Group can reduce our costs associated with involving in prolonged negotiations with new service providers and cooperating with them in run-in period. The procurement of Auxiliary R&D Procurement Services from the Remaining Kelun Group has been conducted in a way following and in compliance with the due internal procurement procedure of our Group;

- (c) the procurement of Auxiliary R&D Procurement Services from the Remaining Kelun Group is carried out by both parties in the ordinary course of business and is on normal commercial terms which are fair and reasonable to our Group and the Remaining Kelun Group. The fees payable by us to the Remaining Kelun Group for procuring the Auxiliary R&D Procurement Services are comparable to the market price; and
- (d) the risk that the Remaining Kelun Group will terminate the relevant agreement in relation to the procurement of the Auxiliary R&D Procurement Services is remote as it has limited termination rights under the relevant agreements, and the termination would not be in the commercial interest of the Remaining Kelun Group. Providers of these Auxiliary R&D Procurement Services are generally available in the market. In an unlikely event that the Remaining Kelun Group terminates the relevant agreement with us, we are able to find substitute providers to offer Auxiliary R&D Procurement Services. As such, we don’t consider such termination will materially and adversely affect our business.

During the Track Record Period and in the ordinary and usual course of business, we have also provided auxiliary R&D services (the “**Auxiliary R&D Provision Services**”) to the Remaining Kelun Group, which include preclinical animal toxicology, pharmacokinetics, pharmacodynamic studies (including screening studies and application studies), clinical biostatistics, data management, quality control and clinical audit, and other supporting services. Such transactions will constitute continuing connected transactions of our Company upon completion of the [REDACTED]. For further details, see “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement and Provision of Auxiliary R&D Services.” Our Company is of the view that such Auxiliary R&D Provision Services provided to the Remaining Kelun Group will not affect our ability to operate independently from the Remaining Kelun Group, as such Auxiliary R&D Provision Services are not the principal business of our Company and we will not rely on the revenue generated from the Auxiliary R&D Provision Services.

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Procurement from Kelun Medicine & Trade Group

During the Track Record Period and in the ordinary and usual course of business, we procured R&D-related drugs and consumables (the “**R&D-related Drugs and Consumables**”) from Kelun Medicine & Trade Group from time to time. Following the [REDACTED], we expect to continue engaging Kelun Medicine & Trade Group to provide these R&D-related Drugs and Consumables on an arm’s length basis and on normal commercial terms. Such transactions will constitute continuing connected transactions of our Company upon completion of the [REDACTED]. For further details, see “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement of R&D-related Drugs and Consumables.” Our Company is of the view that such Procurement from Kelun Medicine & Trade Group will not affect our ability to operate independently from the Remaining Kelun Group since the providers of such R&D-related Drugs and Consumables are generally available in the market and we are able to find substitute providers to provide similar products in the worst scenario that Kelun Medicine & Trade Group ceases to provide relevant products to us.

We have our own procurement team independent from our Controlling Shareholders. Our Controlling Shareholders and we have been and will be carrying out respective selection of suppliers independently in accordance with respective supplier management policies and system. Our procurement team may select supplier candidates from respective supplier list or reach out to supplier candidates, which are not within the list according to specific procurement demand. Our procurement team runs the supplier selection process and the procurement process independently, negotiate the terms of the procurement agreements with suppliers directly and independently.

Leasing properties from the Remaining Kelun Group

Our Group has been operating on the premises located in Wenjiang District, Chengdu. The facilities include a wide range of R&D centers and production lines for R&D and manufacturing of our pipeline products, which are different from and not interchangeable with the R&D centers and production facilities of the Remaining Kelun Group. There is no sharing of production facilities or production personnel between our Group and the Remaining Kelun Group.

We have been leasing certain properties from the Remaining Kelun Group for operation, R&D activities and office space during the Track Record Period and expect to continue leasing properties after the completion of the [REDACTED] to avoid unnecessary relocation cost. It is a common practice in the pharmaceutical industry that a pre-profit biopharmaceutical company operates by leasing premises, and inputs a substantial part of its cash flow into the R&D activities. These leases are recognized as on our statement of financial position as right-of-use assets under IFRS 16 (Leases). As such, such lease transactions will constitute one-off connected transactions of our Company upon [REDACTED]. For further details, see “Connected Transactions – One-off Connected Transactions – Lease of Properties.”

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Our Company is of the view that the ongoing leasing of the properties from the Remaining Kelun Group is unlikely to experience disruption, and will not affect our operational independence, on the basis of the following:

- (a) the risk that the ongoing leases will be terminated and that we will be forced to relocate is extremely low given that (i) as the lease agreements were entered into by the parties after arm’s length negotiations and on normal terms, the Remaining Kelun Group does not have motivation to terminate the leases recklessly; and (ii) the relevant leases have been continuously renewed during the Track Record Period without any disruption;
- (b) we are in the process of constructing three buildings for self-use on the two parcels of land which are close to our current location. The additional space will be used for our R&D activities, manufacturing and office premises. We expect that these three newly-buildings could be put into use in around 2023; and
- (c) the properties are currently located in an industrial park in Chengdu, Sichuan Province, where a large number of lands and buildings are offered for lease in the locality. In the unlikely event that the Remaining Kelun Group terminates the lease agreements with us and we are required to relocate, we expect that there will not be any substantive hurdle for us to find substitutive premises nearby with comparable rental rates.

Leasing equipment from the Remaining Kelun Group

Kelun Group implements a centralized equipment procurement policy under which Kelun Group procures equipment necessary to its subsidiaries’ business and daily operations and then leases these equipment to its subsidiaries for use. Such centralized procurement policy enhances Kelun Group’s bargaining power when negotiating with equipment suppliers which enables Kelun Group to procure these equipment at a favorable price. As a subsidiary of Kelun Group, we have been leasing certain equipment used in connection with our R&D activities and daily operations from the Remaining Kelun Group during the Track Record Period and expect to continue leasing the relevant equipment from the Remaining Kelun Group after completion of the [REDACTED]. By leasing equipment from our Controlling Shareholder, we can input more cash flow into our R&D activities. These leases are recognized as on our statement of financial position as a right-of-use assets under IFRS 16 (Leases). As such, such lease transaction will constitute a one-off connected transaction of our Company upon [REDACTED]. For further details, see “Connected Transactions – One-off Connected Transaction – Equipment Lease Agreement”.

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Our Company is of the view that the ongoing leasing of these equipment from the Remaining Kelun Group is unlikely to experience disruption, and will not affect our operational independence, on the following basis:

- (a) the risk that the ongoing leases will be terminated and that we are no longer able to use the leased equipment is extremely low given that (i) the leased equipment were procured by Kelun Group at the request of us under its centralized equipment procurement policy; (ii) as the lease agreements were entered into by the parties after arm’s length negotiations and on normal commercial terms, the Remaining Kelun Group does not have motivation to terminate the leases recklessly; and (iii) the relevant leases have been continuously renewed during the Track Record Period without any disruption; and
- (b) these equipment are generally available on the market. We expect that there will not be any substantive hurdle for us to find substitutive equipment.

Business development

We have our independent business development teams primarily for commercialization of our drugs. Members of our business development team were recruited by our Group independently. We expect to develop our own sales and marketing network in accordance with the commercialization progress of our drugs.

Overlap with the Remaining Kelun Group in Customers, Suppliers and Collaborators

Suppliers

For the years ended December 31, 2021 and 2022, the total transaction amount with the top 10 suppliers of the Group represented 33.5% and 39.1% of the total procurement amounts of the Group. During the Track Record Period, there were two overlapping parties between the top ten suppliers of the Group and the top ten suppliers of the Remaining Kelun Group, namely Kelun Medicine & Trade and Sichuan Yongcun Construction Engineering Co., Ltd. (四川永存建築工程有限公司) (“**Sichuan Yongcun**”, together with Kelun Medicine & Trade, the “**Overlapping Suppliers**”).

Kelun Medicine & Trade is a connected person of the Company. In the ordinary course of its business, the Company procured R&D-related Drugs and Consumables from Kelun Medicine & Trade and its subsidiaries during the Track Record Period, which were with high quality, stable and quick delivery at reasonable prices. The Company expects to continue such procurement after the [REDACTED]. Please refer to “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement of R&D-related Drugs and Consumables” for details. The total transaction amounts between the Group and Kelun Medicine & Trade accounted for approximately 1.3% and 2.4% of the Group’s total procurement amounts for the years ended December 31, 2021 and 2022, respectively.

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Sichuan Yongcun is an Independent Third Party to the Company. The Company procured construction services from Sichuan Yongcun during the Track Record Period. The total transaction amounts between the Group and Sichuan Yongcun accounted for approximately 12.5% and 5.0% of the Group’s total procurement amounts for the years ended December 31, 2021 and 2022, respectively.

Our Company believes that the Overlapping Suppliers do not affect the business delineation between the Group and the Remaining Kelun Group, or result in reliance by the Group on the Remaining Kelun Group, on the following basis:

- (a) the Group and the Remaining Kelun Group have been and will be carrying out their selection of suppliers independently in accordance with their respective supplier management system. The Group has established its own supplier list, which is separate from the Remaining Kelun Group. The respective procurement teams of the Group and the Remaining Kelun Group may select supplier candidates from their respective supplier list or reach out to supplier candidates which are not within the list according to their specific procurement demand. The respective procurement teams of the Group and the Remaining Kelun Group are responsible for the supplier selection process and the procurement process independently, and they negotiate the terms of the procurement agreements with the suppliers directly and independently. The Group has full discretion to select its suppliers, and all the terms of the procurement agreements are negotiated between the Group and the suppliers directly and independently;
- (b) the total transaction amounts between the Overlapping Suppliers and the Group were immaterial during the Track Record Period;
- (c) the qualification, capability and satisfactory cooperation history of the suppliers are the reasons that the Group procures the relevant products and services from them, instead of their business relationship with the Remaining Kelun Group; and
- (d) the R&D-related Drugs and Consumables provided by Kelun Medicine & Trade; and the construction services provided by Sichuan Yongcun can be readily sourced from other third-party suppliers.

Customers

The Group is an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs. During the Track Record Period, given none of the Group’s products had been commercialized, the number of Group’s customers are quite limited. For the years ended December 31, 2021 and 2022, other than the Remaining Kelun Group, the Group had four and five customers in total, respectively. During the same year, the Group and the Remaining Kelun Group did not have overlapping customers.

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In addition, there were no bundled sales from, or bundled suppliers and/or services rendered to, the Group and the Remaining Kelun Group during the Track Record Period.

Collaborators

The Group has established robust, cross-border business development capabilities with local presence across multiple jurisdictions, from Chengdu, Beijing and Shanghai in China to New Jersey in the U.S. The Group’s business development team is led by seasoned professional with extensive experience and insights in sourcing and executing licensing deals and collaborations. In addition, the Group also collaborates with CROs to advance its clinical development programs. As disclosed above, for the years ended December 31, 2021 and 2022, (i) there were two overlapping parties between the top ten suppliers of the Group and the top ten suppliers of the Remaining Kelun Group (i.e., Kelun Medicine & Trade and Sichuan Yongcun), both of which are not collaborators of the Group; and (ii) the Group and the Remaining Kelun Group did not have any overlapping customers.

Administration

Our Group has full-time management team and team of staff to carry out our own administration and operation independent of the Remaining Kelun Group. The support services comprising accounting, administration, corporate secretarial, compliance and human resource management will also continue to be handled by a team of staff employed directly by our Group and separated from the Remaining Kelun Group. As all these key administrative functions of our Group will be carried out by us without reliance on the support of the Remaining Kelun Group, our Group will remain administratively independent upon completion of the [REDACTED].

Connected transactions with our Controlling Shareholders

The connected transactions set out in “Connected Transactions” of this document were and will be conducted in the ordinary and usual course of business of our Group, on an arm’s length basis and on normal commercial terms or better. Furthermore, the risk of our Controlling Shareholders terminating the connected transactions is remote as the parties under the relevant agreements have limited termination rights and the termination would not be in the commercial interest of our Controlling Shareholders in commercial aspect. In an unlikely event that our Controlling Shareholders terminate any connected transaction with us, given the reasons set out in “Connected Transactions” of this document, we do not consider such termination will materially and adversely affect our business. For further details, see “Connected Transactions”.

Sharing of personnel, premises, facilities and other resources

Historically, certain of our R&D team members were initially staffed within the Remaining Kelun Group and had been transferred to our Group after our establishment in 2016. As of the Latest Practicable Date, none of our R&D team members held any position in the Remaining Kelun Group, and no R&D personnel employed by the Remaining Kelun Group had any meaningful contribution in the development of our Core Products and other pipeline candidates. See also “Business – Research and Development – In-house R&D.” We entered into certain connected transactions with the Remaining Kelun Group, which involve, among others, property leasing, equipment leasing, trademark licensing, and shared administrative services. For further details, see “Connected Transactions”.

Save as disclosed above, there is no sharing of personnel, premises, facilities and other resources between the Group and the Remaining Kelun Group.

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Measures to Reduce Reliance

R&D

We have our own R&D center independent from that of the Remaining Kelun Group. All of our R&D team are full-time employees of the Group not holding any position in the Remaining Kelun Group. Currently, all of the Group’s fundamental and core on-going R&D activities, including preclinical studies and clinical trials are conducted independently by our R&D team without reliance on the Remaining Kelun Group. We have historically procured auxiliary R&D services, including process development and optimization, sample purification, crystallization screening, GMP batch release testing, and other auxiliary R&D services from the Remaining Kelun Group. These auxiliary R&D services provided by the Remaining Kelun Group are not core to our R&D activities, and are generally available in the market. In addition, considering the anticipated increasing improvement of our R&D capabilities, we estimate that the transaction amounts payable by us to the Remaining Kelun Group will decrease incrementally from 2023 to 2025.

Manufacturing

We have built our own manufacturing facilities designed in compliance with the NMPA and FDA’s regulatory requirements and cGMP standards in China, the U.S. and Europe to meet the manufacturing challenges associated with the production of complex molecules. We have built a dedicated manufacturing site in Chengdu with a total floor area of over 10,600 m². In anticipation of the increased demand upon commercialization, we are actively evaluating the addition of new manufacturing facilities and the expansion of existing manufacturing facilities. For our cell culture and purification unit, we plan to install one additional 2,000 L single-use bioreactor, bring our total in-house capacity to 6,000 L. Going forward, we will continue to enhance our manufacturing capabilities, both through expanding our in-house capacity and through collaboration with industry-recognized CMOs.

Quality Control

We have established a comprehensive quality control system that extends across all key stages of the R&D, manufacturing and commercialization processes. We have also established our own quality control and quality assurance procedures to ensure that our manufacturing processes comply with relevant regulatory requirements and internal quality standards. As of December 31, 2022, our quality management team comprised over 150 members. They oversee the quality systems covering all key stages of our drug development process, from R&D, manufacturing to commercialization, including discovery, preclinical research and discovery, clinical trials, procurement, supply chain, process development, production, warehousing, delivery and recalls.

Business Development

We have established our own robust, cross-border business development capabilities with local presence across multiple jurisdictions, from Chengdu, Beijing and Shanghai in China to New Jersey in the U.S. Our business team is led by seasoned professionals with decades-long experience and insights in sourcing and executing licensing deals and collaborations. Our business development competencies are exemplified by a proven track record in forging strategic partnership worldwide. Notably, we have independently and successfully negotiated nine out-license agreements to date, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Commercialization

We will be benefiting from the Remaining Kelun Group’s decades-long experience, industry connection and extensive network when developing our own commercialization infrastructure and market access. However, given the differences in novel drugs and generic drugs, we have different key target customers with the Remaining Kelun Group.

As we focus on R&D, manufacturing and commercialization of novel drugs, our target customers primarily consist of Class III hospitals with demand for novel drugs to address medical needs. Given the nature of novel drugs, there is no similar labeling requirement which applies to generic drugs. As such, physician prescribing behavior in respect of novel drugs is usually influenced by education conducted by novel drug developers. By contrast, physicians usually prescribe generic drugs by strictly following generic drug labeling, which is the same as the last approved reference listed drug labeling except for permissible difference. As such, for novel drugs, close interaction and cooperation with leading physicians at Class III hospitals would be critical to the successful promotion of our products. Therefore, we are in the process of building our own commercialization infrastructure and expanding our sales and marketing network, with an initial focus on Class III hospitals and leading physicians across China’s extensive local markets. It is expected that we will have a fully-fledged commercialization team by the end of 2023 to oversee and coordinate the commercialization of our late-stage assets.

With respect to target customers other than Class III hospitals and leading physicians, we plan to leverage Kelun Pharmaceutical’s industry connection and extensive network as well as collaborating with third party CSOs, to expand potential reach of our products to China’s extensive local markets to the maximum extent possible. We will independently evaluate the terms of collaborations taking into account all relevant factors as we consider necessary. A decision on whether to enter into any sales service agreement with either Kelun Pharmaceutical or third party CSOs will be made purely based on commercial considerations and only if we consider it is in the best interest of our Company and the Shareholders as a whole. We will comply with the announcement, circular and/or independent Shareholders’ approval requirements under Chapter 14A of the Listing Rules if any transaction is to be entered into with Kelun Pharmaceutical.

Procurement

We have been and will be carrying out our selection of suppliers independently in accordance with our supplier management system. Our procurement team runs the supplier selection process and procurement process independently. It is responsible for (i) selecting supplier candidates from the supplier list or reaching out to supplier candidates which are not within the list according to the specific procurement demand; and (ii) negotiating the terms of the procurement agreements with suppliers directly and independently.

Leased Properties from Kelun Pharmaceutical

We have been leasing the relevant properties from Kelun Pharmaceutical during the Track Record Period. However, we have already obtained land use rights to two parcels of land in Chengdu, PRC, with an aggregate site area of approximately 132,341.8 m², and are in the process of constructing three buildings for our own use on the two parcels of land. The additional space will be used for our R&D activities, manufacturing and office premises, which could be put into use in around 2023.

Based on the above, our Directors believe that we are able to operate independently of our Controlling Shareholders.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Financial Independence

Our Company has established its own finance department with a team of independent financial staff responsible for discharging treasury, accounting, reporting, group credit and internal control functions independent from our Controlling Shareholders, as well as a sound and independent financial system, and makes independent financial decisions according to our business needs. We have independent internal control and accounting systems. We are capable of obtaining financing from third parties, if necessary, without reliance on our Controlling Shareholders.

During the Track Record Period, our Controlling Shareholders provided guarantees in respect of certain bank borrowings by our Group (the “**Guaranteed Loans**”). Please refer to note 21 of the Accountants’ Report in Appendix I to this document for further details. As of the Latest Practicable Date, all the outstanding principal amount of the Guaranteed Loans and the accrued interest under the Guaranteed Loans had been fully repaid by us.

During the Track Record Period, Kelun Pharmaceutical provided certain shareholder loans (the “**Controlling Shareholder Loans**”) to support our day-to-day operations and business. It is common for pre-profit biopharmaceutical companies like us to obtain shareholder loan to support its operations and business. The terms of the Controlling Shareholder Loan were negotiated between Kelun Pharmaceutical and us on an arm’s length basis and on normal commercial terms. On January 3, 2023, our Company, Kelun Pharmaceutical and the other then Shareholders of the Company entered into a share subscription and debt-to-equity swap agreement, pursuant to which Kelun Pharmaceutical agreed to further subscribe for an aggregate of 51,255,685 Shares at the total subscription price of RMB2.65 billion, among which RMB2.5 billion was settled through debt-to-equity swap. For further details, see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing – Share Subscription by Kelun Pharmaceutical”. As of the Latest Practicable Date, all the remaining outstanding principal amount and accrued interest under the Controlling Shareholder Loans had been fully repaid by us. No loans or guarantees provided by, or granted to, our Controlling Shareholders or its respective associates will be outstanding as of the [REDACTED].

During the Track Record Period, we had amounts due to related parties of a non-trade nature, which primarily represented the consideration to be paid to Kelun Development for the transfer of shares in KLUS PHARMA. see “History – Our Subsidiaries – KLUS PHARMA.” As of the Latest Practicable Date, we had settled such outstanding balance in full.

Based on the above, our Directors are of the view that we are capable of carrying on our business independently of, and do not place undue reliance on our Controlling Shareholders and its close associates after the [REDACTED].

CORPORATE GOVERNANCE MEASURES

Our Company and Directors are committed to upholding and implementing the highest standards of corporate governance and recognize the importance of protecting the rights and interests of all Shareholders, including the rights and interests of our minority Shareholders. We will comply with the provisions of the Corporate Governance Code set forth in Appendix 14 to the Listing Rules, which sets out the principles of good corporate governance.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Our Company is also required to comply with the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules, which provides, among other matters, prohibitions on directors and supervisors' dealings in securities and protection of minority Shareholders' rights.

Additionally, we will also adopt the following measures to ensure good corporate governance standards and to avoid potential conflicts of interest between our Group and our Controlling Shareholders:

- (a) as part of our preparation for the [REDACTED], we have amended our Articles of Association to comply with the Listing Rules. In particular, our Articles of Association provided that, unless otherwise provided, a Director shall not vote on any resolution approving any contract or arrangement or any other proposal in which such Director or any of his or her associates have a material interest nor shall such Director be counted in the quorum present at the meeting;
- (b) our independent non-executive Directors shall review, at least on an annual basis, the compliance with the Deed of Non-competition by our Controlling Shareholders. Each of our Controlling Shareholders shall and shall procure his/its relevant close associates to provide all information necessary for the annual review by our independent non-executive Directors for the enforcement of the Deed of Non-competition;
- (c) we shall disclose the review by our independent non-executive Directors on the compliance with, and the enforcement of, the Deed of Non-competition and the decisions on matters reviewed by our independent non-executive Directors either through our annual report or by way of announcement to the public in compliance with the Listing Rules;
- (d) each of our Controlling Shareholders will make an annual declaration in our annual report on the compliance with their respective deeds of non-competition in accordance with the principle of voluntary disclosure in the corporate governance report;
- (e) a Director with material interests shall make full disclosure in respect of matters that may have conflict or potential conflict with any of our interest and abstain from participation of the board meetings on matters in which such Director or his or her associates have a material interest, unless the attendance or participation of such Director at such meeting of our Board is specifically requested by a majority of the independent non-executive Directors. When such conflict or potential conflict arises, the Board will have a sufficient number of independent non-executive directors who have requisite industry experience to advise on any conflicted transactions;
- (f) our Company has established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if our Company enters into connected transactions with our Controlling Shareholders or any of their associates, our Company will comply with the applicable Listing Rules;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (g) as required by the Listing Rules, our independent non-executive Directors shall review connected transactions annually and confirm in our annual report that such transactions have been entered into in our ordinary and usual course of business, are on normal commercial terms or better and on terms that are fair and reasonable and in the interests of our Shareholders as a whole;
- (h) should there be a conflict of interest or a connected transaction between our Company (on one hand) and our Controlling Shareholders (on the other hand), the relevant overlapping directors will abstain from voting on, and will not be counted in the quorum for, the relevant board resolution(s) of our Company;
- (i) we are committed that our Board should include a balanced composition of executive Directors and independent non-executive Directors. We have appointed independent non-executive Directors and we believe our independent non-executive Directors possess sufficient experience and they are free of any business or other relationship which could interfere in any material manner with the exercise of their independent judgment. The independent non-executive Directors will review, on an annual basis, whether there are any conflicts of interests between our Group and our Controlling Shareholders and provide impartial and professional advice to protect the interests of our minority Shareholders;
- (j) we have appointed First Shanghai Capital Limited as our compliance advisor to provide advice and guidance to us in respect of compliance with the applicable laws and regulations, as well as the Listing Rules, including various requirements relating to corporate governance; and
- (k) we have established our audit committee, remuneration committee and nomination committee with written terms of reference in compliance with the Listing Rules and the Code on Corporate Governance and Corporate Governance Report in Appendix 14 to the Listing Rules. All of the members of our audit committee, including the chairman, are independent non-executive Directors.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest that may arise between our Group and our Controlling Shareholders, and to protect our minority Shareholders’ interests after the [REDACTED].

CONNECTED TRANSACTIONS

OVERVIEW

Prior to the [REDACTED], our Company has entered into certain transactions with parties who will, upon the [REDACTED], become connected persons of the Company. We will continue to engage in certain connected transactions after the [REDACTED]. Details of such one-off connected transactions and continuing connected transactions of our Company under Chapter 14A of the Listing Rules upon [REDACTED] are set out below.

RELEVANT CONNECTED PERSONS

The table below sets forth certain parties who will become our connected persons upon [REDACTED] and the nature of their relationships with our Company:

Connected Persons	Connected Relationship
Kelun Pharmaceutical (including its subsidiaries other than our Group)	Kelun Pharmaceutical is our Controlling Shareholder.
Sichuan Kelun Pharmaceutical Research Institute Co., Ltd. (四川科倫藥物研究院有限公司) (“ Kelun Research Institute ”)	Kelun Research Institute is a wholly-owned subsidiary of Kelun Pharmaceutical and a connected person to us.
Sichuan Kelun Medicine & Trade Group Co. Ltd. (四川科倫醫藥貿易集團有限公司) (“ Kelun Medicine & Trade ”) (including its subsidiaries)	Kelun Medicine & Trade is held as to (i) 68.2% by Sichuan Huifeng Investment Development Co., Ltd (四川惠豐投資發展有限責任公司), a company controlled by our Director Mr. Liu Sichuan, (ii) 29.8% by Sichuan Kelun Industrial Group Co., Ltd (四川科倫實業集團有限公司), a company controlled by our Director Mr. Liu Gexin and (iii) 2% by Mr. Liu Sichuan directly. Therefore, Kelun Medicine & Trade is an associate of Mr. Liu Sichuan and a connected person to us.

CONNECTED TRANSACTIONS

ONE-OFF CONNECTED TRANSACTIONS

Lease of Properties

Historically, we leased certain land-use-right and properties from Kelun Pharmaceutical. We entered into a property lease agreement (the “**Property Lease Agreement**”) with Kelun Pharmaceutical, pursuant to which, we agreed to lease properties with a total gross area of approximately 35,000 sq.m. located at Wenjiang District, Chengdu from Kelun Pharmaceutical with a term of three years commencing on January 1, 2022. The leased properties under the Property Lease Agreement are used by our Company for daily operations and business, such as R&D activities, storage house, office spaces and staff housing. The Land Lease Agreement and the Property Lease Agreement were entered into (i) in the ordinary and usual course of business of our Group, (ii) on arm’s length basis, and (iii) on normal commercial terms or better with the rents being agreed with reference to the prevailing markets rates of comparable properties in the locality and acreage of the properties, which have been assessed by Cushman & Wakefield Limited, an independent property valuer engaged by our Company.

The balance of the lease liabilities, being the present value of the lease payments recognized by our Group in relation to the Land Lease Agreement and the Property Lease Agreement according to IFRS16 as of December 31, 2022 amounted to RMB21.4 million. As of December 31, 2021 and 2022, the right-of-use assets in connection with the Land Lease Agreement and relevant property lease agreements were approximately RMB1.1 million and RMB13.6 million, respectively.

Reasons and Benefits of the Transaction

It is a common practice in the pharmaceutical industry that a pre-profit biotech company, like us, operates by leasing properties so as to allocate a substantial part of its cash flow into R&D activities.

We have been leasing the relevant properties from Kelun Pharmaceutical during the Track Record Period. Continuous leasing the relevant properties from Kelun Pharmaceutical can reduce our costs associated with looking for new premises and involving in prolonged negotiations of lease agreements with third party property’s owners. Additionally, given that any relocation of facility or change of the current arrangements under the currently effective property lease agreement may cause certain disruption to our business operation and incur additional relocation costs, it is cost efficient and beneficial to our operations to continue leasing the relevant properties from Kelun Pharmaceutical. In light of the foregoing, our Directors are of the view that such arrangement is fair and reasonable and in the best interest of our Group and our Shareholders as a whole.

CONNECTED TRANSACTIONS

Notwithstanding the above, such arrangement under the Land Lease Agreement and the Property Lease Agreement does not affect our operational independence. For further details, see “Relationship with our Controlling Shareholders – Independence of Our Group from Our Controlling Shareholder – Operational Independence – Leasing properties from our Controlling Shareholder.”

Listing Rules Implications

IFRS 16 (Leases) (which became effective from January 1, 2019) requires a lessee to recognize assets and liabilities for lease with a term of more than 12 months. A lessee is required to recognize a right-of-use asset representing its right to use the underlying leased asset and a lease liability representing its obligation to make lease payments in future. In accordance with IFRS 16, our Group recognized a right-of-use asset on the statement of financial position in connection with the lease under the Land Lease Agreement and the Property Lease Agreement. Therefore, the leases under the Land Lease Agreement and the Property Lease are regarded as an acquisition of a capital asset of our Group and a one-off connected transaction entered into by our Group prior to the [REDACTED], rather than a continuing connected transaction, for the purposes of the Listing Rules. Accordingly, the reporting, announcement, annual review, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules will not be applicable.

Equipment Lease Agreement

Kelun Pharmaceutical, our Controlling Shareholder, implements a centralized equipment procurement policy under which Kelun Pharmaceutical procures equipment necessary to its subsidiaries’ business and daily operations and then leases these equipment to its subsidiaries for use. Such centralized procurement policy has strengthened Kelun Pharmaceutical’s bargaining power when negotiating with equipment suppliers and therefore enables Kelun Pharmaceutical to procure these equipment at a favorable price. As a subsidiary of Kelun Pharmaceutical, we have been leasing certain equipment used in connection with our R&D activities and daily operations from Kelun Pharmaceutical under such arrangement. We have been entering into an equipment lease agreement with Kelun Pharmaceutical on a yearly basis for a term of one year since 2019, covering the term of each of the year of 2019, 2020 and 2021.

Our Company further entered into a new equipment lease agreement (the “**Equipment Lease Agreement**”) with Kelun Pharmaceutical, pursuant to which, our Group agreed to lease certain equipment used in connection with our R&D activities and daily operations from Kelun Pharmaceutical with a term of three years commencing on January 1, 2022. The Equipment Lease Agreement was entered into (i) in the ordinary and usual course of business of our Group, (ii) on arm’s length basis, and (iii) on normal commercial terms or better with the rents being agreed with reference to (i) the acquisition cost of these equipment incurred by Kelun Pharmaceutical; and (ii) the results of valuation of such equipment prepared by an independent external appraiser.

CONNECTED TRANSACTIONS

The balance of the lease liabilities, being the present value of the lease payments recognized by our Group in relation to the relevant equipment lease agreement according to IFRS16 as of December 31, 2022 amounted to RMB101.5 million. As of December 31, 2021 and 2022, the right-of-use assets in connection with the relevant equipment lease agreements were nil and RMB64.6 million, respectively.

Reasons and Benefits of the Transaction

As discussed above, under the centralized equipment procurement policy, Kelun Pharmaceutical has been procuring equipment necessary for its subsidiaries’ business and daily operations and then leasing these equipment to its subsidiaries including us. Such centralized procurement policy enables Kelun Pharmaceutical to procure these equipment at a favorable price. Under such equipment lease arrangement, we do not need to contribute a significant portion of our funds to procure equipment necessary for our R&D activities and daily operations so that we can allocate a substantial part of our cash flow into R&D activities. In light of the foregoing, our Directors are of the view that such arrangement is fair and reasonable and in the best interest of our Group and our Shareholders as a whole.

Notwithstanding the above, such arrangement under the Equipment Lease Agreement does not affect our operational independence. For further details, see “Relationship with our Controlling Shareholders – Independence of Our Group from Our Controlling Shareholder – Operational Independence – Leasing equipment from our Controlling Shareholder.”

Listing Rules Implications

IFRS 16 (Leases) (which became effective from January 1, 2019) requires a lessee to recognize assets and liabilities for lease with a term of more than 12 months. A lessee is required to recognize a right-of-use asset representing its right to use the underlying leased asset and a lease liability representing its obligation to make lease payments in future. In accordance with IFRS 16, our Group recognized a right-of-use asset on the statement of financial position in connection with the lease under the Equipment Lease Agreement. Therefore, the lease under the Equipment Lease Agreement is regarded as an acquisition of a capital asset of our Group and a one-off connected transaction entered into by our Group prior to the [REDACTED], rather than a continuing connected transaction, for the purposes of the Listing Rules. Accordingly, the reporting, announcement, annual review, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules will not be applicable.

CONNECTED TRANSACTIONS

CONTINUING CONNECTED TRANSACTIONS

The following table sets forth a summary of our continuing connected transactions upon [REDACTED]:

Transaction	Applicable Listing Rules	Waiver Sought	Proposed Annual Caps for the years ending December 31,		
			2023	2024	2025
<i>(RMB in thousands)</i>					
Fully exempt continuing connected transactions					
Trademark License Agreements	14A.52, 14A.76(1)(a)	N/A	N/A	N/A	N/A
Shared Administrative Services Framework Agreement	14A.98	N/A	N/A	N/A	N/A
Partially exempt continuing connected transactions					
Auxiliary R&D Services Framework Agreement	14A.34 to 14A.36, 14A.49, 14A.51 to 14A.59 and 14A.71	Waiver from announcement requirement	<i>In terms of procurement of services from the Remaining Kelun Group</i>		
			22,000	18,000	15,000
			<i>In terms of provision of services to the Remaining Kelun Group</i>		
			16,000	16,000	16,000
R&D-related Drugs and Consumables Framework Agreement	14A.34 to 14A.36, 14A.49, 14A.51 to 14A.59 and 14A.71	Waiver from announcement requirement	20,000	40,000	30,000
Non-exempt continuing connected transaction					
Licensing Agreement	14A.34 to 14A.36, 14A.49, 14A.51 to 14A.59 and 14A.71	Waiver from monetary annual cap, announcement requirement, circular, and independent shareholders' approval requirements	N/A	N/A	N/A

CONNECTED TRANSACTIONS

FULLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

We set out below a summary of the continuing connected transactions for our Group, which will be exempt from the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

Trademark Licensing Agreement

Our Group and Kelun Pharmaceutical entered into a trademark licensing agreement (the “**Trademark Licensing Agreement**”) on November 5, 2022, pursuant to which Kelun Pharmaceutical agreed to exclusively grant us the rights to use certain trademarks which have been or are being registered by Kelun Pharmaceutical in the PRC and the United Kingdom for our use in connection with our operations on a royalty-free basis for a term commencing from the date of the agreement and continue to be in force and effect until the date when the term of all such licensed trademarks under the Trademark Licensing Agreement expire, being April 6, 2028. In order to ensure our continuous use of such licensed trademarks, Kelun Pharmaceutical also agreed that unless otherwise agreed by the parties, the term of the Trademark Licensing Agreement will be automatically extended if the terms of the relevant licensed trademarks under the Trademark Licensing Agreement are renewed after expiry.

As the usage right of the trademarks were granted by Kelun Pharmaceutical to us is on a royalty-free basis, the transactions under the Trademark Licensing Agreement fall within the de minimis threshold under Rule 14A.76(1)(a) of the Listing Rules and are exempt from the annual review, reporting, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

Rule 14A.52 of the Listing Rules provides that the period for the agreement of a continuing connected transaction must not exceed three years except in special circumstances where the nature of the transaction requires a longer period. Our Directors are of the view that the nature of Trademark Licensing Agreement requires a longer period based on the grounds that (i) the Trademark License Agreement is on a royalty-free basis and allows our Group to use the licensed trademarks of Kelun Pharmaceutical during the daily business operations, which is long term in nature. Imposing a restriction on the term of the Trademark Licensing Agreement for a period of three years would deviate from the market prevailing practice and be contrary to the business intention of the parties; (ii) such a perpetual term of trademark licensing agreement can ensure the stable use of the relevant trademarks by our Group, which is in the interest of our Company and the Shareholders as a whole; and (iii) as confirmed by Frost & Sullivan, the term of the Trademark Licensing Agreement, which exceeds three years, is in line with the industry prevailing practice.

Shared Administrative Services Framework Agreement

We have historically shared with the Remaining Kelun Group certain administrative services such as catering, utilities, shuttle bus operation, office park greening, office space cleaning and staff dormitory services (the “**Shared Administrative Services**”) in our ordinary and usual course of business. We intend to continue such arrangement with the Remaining Kelun Group after the [REDACTED]. On [●], 2023, our Company and Kelun Pharmaceutical (for itself and on behalf of the Remaining Kelun Group) entered into a shared administrative services framework agreement (the “**Shared Administrative Services Framework Agreement**”), pursuant to which the Remaining Kelun Group shall provide the Shared Administrative Services to us. The Shared Administrative Services will be charged to us on a cost basis, and the relevant costs (i) are made reference to the prevailing prices for similar

CONNECTED TRANSACTIONS

services readily on the market; and (ii) must be identifiable and allocated to us based on the actual expenses incurred by us. Our Directors consider that the sharing of the Shared Administrative Services between the Remaining Kelun Group and our Group under the Shared Administrative Services Framework Agreement would allow our Group to take advantage of bulk purchasing of resources at lower average costs and to enjoy economies of scale brought by the sharing of the Shared Administrative Services which would maximize cost efficiency and optimize the overall administrative cost structure.

The Shared Administrative Services Framework Agreement will commence from the [REDACTED] and continue until December 31, 2025 (both days inclusive). Subject to compliance with Listing Rules and applicable laws and regulations, the Shared Administrative Services Framework Agreement may be renewed for a further term of three years from time to time, unless either party notifies the other party to the contrary with three months’ written notice prior to the expiry of the agreement’s term.

As the Shared Administrative Services will be shared between the Remaining Kelun Group and our Group on a cost basis where the costs (being costs paid by the Remaining Kelun Group to their suppliers and/or their labor costs based on relevant work hours) will be identifiable and allocated to the parties on a fair and equitable basis, pursuant to Rule 14A.98 of the Listing Rules, the Shared Administrative Services Framework Agreement will be exempt from the announcement, circular, independent Shareholders’ approval, reporting and annual review requirements under Chapter 14A of the Listing Rules.

PARTIALLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

Procurement and Provision of Auxiliary R&D Services

We have historically procured auxiliary R&D services, which include process development and optimization, sample purification, crystallization screening, GMP batch release testing, packing material and releasing testing from the Remaining Kelun Group, and have provided auxiliary R&D services, which include preclinical animal studies (including toxicology, pharmacokinetics, pharmacodynamic and screening studies), clinical biostatistics, data management, quality control and clinical audit, and other supporting services, to the Remaining Kelun Group (collectively, the “**Auxiliary R&D Services**”) from time to time in our ordinary and usual course of business. We intend to continue such procurement and provision of services with the Remaining Kelun Group after the [REDACTED]. On [●] 2023, our Company and Kelun Pharmaceutical (for itself and on behalf of the Remaining Kelun Group) entered into a framework agreement in relation to the procurement of the Auxiliary R&D Services (the “**Auxiliary R&D Services Framework Agreement**”), pursuant to which Kelun Pharmaceutical (for itself and on behalf of the Remaining Kelun Group) agreed to provide and procure the Auxiliary R&D Services to/from our Group.

CONNECTED TRANSACTIONS

Principal Terms

The term of the Auxiliary R&D Services Framework Agreement will commence from the [REDACTED] and continue until December 31, 2025 (both days inclusive). Subject to compliance with Listing Rules and applicable laws and regulations, the Auxiliary R&D Services Framework Agreement may be renewed for a further term of three years from time to time, unless either party notifies the other party to the contrary with three months' written notice prior to the expiry of the agreement's term. Upon renewal of the Auxiliary R&D Services Framework Agreement, the parties may amend the terms of the agreement based on the then prevailing circumstances.

Pricing Policy

The services fees have been and will be based on cost-plus basis according to (i) the actual cost of provisions of such services (such as the labor cost and the cost of consumables used for providing the services); plus (ii) the agreed margin rates. The margin rates are determined through arm's length negotiation with reference to the range between the lower quartile and the upper quartile of the three-year weighted average cost-plus-margins of comparable companies offering similar services as stated in a transfer pricing analysis report prepared by an independent certified public accountant. Such margin rates may be changed from time to time and shall not be deemed to be the fixed rate for the transactions throughout the term of the Auxiliary R&D Services Framework Agreement.

Each of the services provided by the Remaining Kelun Group can be readily sourced from third-party suppliers. We have been identifying alternative suppliers for such services and we will continue to engage the Remaining Kelun Group to provide such services only if they are provided to our Group on normal commercial terms or better when compared with other third-party suppliers.

Reasons for and Benefits of the Transaction

The Auxiliary R&D Services provided by the Remaining Kelun Group are not core to our R&D activities. It is common for pre-profit biopharmaceutical companies like us to outsource these auxiliary R&D services to third parties so the pre-profit biopharmaceutical companies can concentrate on core R&D of their drug candidates. We have been engaging the Remaining Kelun Group to provide the Auxiliary R&D Services because (i) the Remaining Kelun Group has competent and reliable expertise in providing such Auxiliary R&D Services and can provide such services at arm's length and with good quality; and (ii) we have been cooperating with the Remaining Kelun Group for the Auxiliary R&D Services for a number of years and the Remaining Kelun Group is familiar with our quality requirement for these services. In addition, we have been providing Auxiliary R&D Services to the Remaining Kelun Group. The Remaining Kelun Group will continue to procure the Auxiliary R&D Services from us because our integrated drug development capabilities have been proven to meet the needs and requirements of the Remaining Kelun Group. Continuous procuring and providing the Auxiliary R&D Services from/to the Remaining Kelun Group can reduce our costs associated with involving in prolonged negotiations with new service providers and customers, and cooperating with them in run-in period.

CONNECTED TRANSACTIONS

We believe that the risk of the Remaining Kelun Group terminating the connected transactions under the Auxiliary R&D Services Framework Agreement is remote as the parties under this agreement have limited termination rights and the termination would not be in the commercial interest of the Remaining Kelun Group. In an unlikely event that the Remaining Kelun Group terminates the connected transactions under the Auxiliary R&D Services Framework Agreement with us, given (i) that the Auxiliary R&D Services we procured can be readily sourced from suppliers who are Independent Third Parties, and (ii) that the Auxiliary R&D Services we supplied to the Remaining Kelun Group is not a part of our primary business, we don't consider such termination will materially and adversely affect our business. Accordingly, we believe that our procurement and provision of the Auxiliary R&D Services from/to the Remaining Kelun Group does not constitute any undue reliance on it. For details, please see “Relationship with our Controlling Shareholders – Independence of Our Group from our Controlling Shareholder – Operational Independence – Research and Development.”

Corporate Governance Measures

In order to ensure that the aforesaid pricing basis for the Auxiliary R&D Services Framework Agreement is adhered to, the Group will monitor the relevant costs to ensure that the selling price of such services are determined properly. The Company and the Remaining Kelun Group will (i) negotiate the terms of such transactions to ensure that prices are fair and reasonable, and properly reflect the level of costs incurred by both parties in the such transactions; (ii) determine the margin rate with reference to a transfer pricing analysis report prepared by an independent certified public accountant or an institution with the same qualification; and (iii) review the scope of Auxiliary R&D Services on a yearly basis (or more frequently if it is determined necessary) to determine whether updated transfer pricing analysis report shall be obtained for the determination of the margin rate. The margin rate will be determined with reference to the lower quartile and upper quartile of the three-year weighted average cost-plus-margins of the comparable companies as stated in such updated transfer pricing analysis report.

Historical Amounts

The following table sets forth the historical amounts of procurement of the Auxiliary R&D Service by our Group from the Remaining Kelun Group for the years ended December 31, 2021 and 2022:

	For the year ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
<i>In terms of procurement of services from the Remaining Kelun Group:</i>		
	74,147	15,666
<i>In terms of provision of services to the Remaining Kelun Group:</i>		
	19,919	16,190

CONNECTED TRANSACTIONS

Annual Caps and Basis of Annual Caps

The following table sets forth the proposed annual caps for the amounts payable by our Group to the Remaining Kelun Group in respect of the procurement of the Auxiliary R&D Services under the Auxiliary R&D Services Framework Agreement:

Proposed annual cap for the year ending December 31,		
2023	2024	2025
<i>(RMB in thousands)</i>		
22,000	18,000	15,000

The proposed annual caps are determined based on the following factors:

- (i) the fee rates of the Auxiliary R&D Services charged by the Remaining Kelun Group and the expected fluctuation in the rate;
- (ii) the historical transaction amounts in respect of our procurement of the Auxiliary R&D Services from the Remaining Kelun Group;
- (iii) the anticipated demand for the Auxiliary R&D Services from the Remaining Kelun Group driven by the R&D progress of our product candidates for the next three years, taking into account the anticipated improvement of our R&D capabilities; and
- (iv) the relevant service provision capacity of Remaining Kelun Group in providing Auxiliary R&D Services.

The following table sets forth the proposed annual caps for the amounts payable by the Remaining Kelun Group to us in respect of the provision of the Auxiliary R&D Services under the Auxiliary R&D Services Framework Agreement:

Proposed annual cap for the year ending December 31,		
2023	2024	2025
<i>(RMB in thousands)</i>		
16,000	16,000	16,000

The proposed annual caps are determined based on the following factors:

- (i) the fee rates of the Auxiliary R&D Services charged by us and the expected fluctuation in the rate;
- (ii) the historical transaction amounts in respect of our provision of the Auxiliary R&D Services to the Remaining Kelun Group;

CONNECTED TRANSACTIONS

- (iii) the anticipated demand for the Auxiliary R&D Services from us; and
- (iv) the relevant service provision capacity of our Group in providing Auxiliary R&D Services.

Listing Rules Implications

As our Group is eligible for listing on the Stock Exchange under Chapter 18A of the Listing Rules and the revenue we record during the Track Record Period was not derived from R&D, manufacturing and commercialization of novel drugs, the calculation of revenue ratio under Rule 14.07 of the Listing Rules is inappropriate to the sphere of activity of our Group, and thus we consider it inapplicable. As an alternative, we have applied a percentage ratio test based on the total expenses for R&D and general and administrative matters of our Group.

As the highest of all applicable percentage ratios (as defined in Rule 14.07 of the Listing Rules) in respect of the proposed annual caps of the Auxiliary R&D Services Framework Agreement will be no less than 0.1% but will not exceed 5%, the transactions under the Auxiliary R&D Services Framework Agreement are continuing connected transactions exempt from the circular (including independent financial advice) and shareholders’ approval requirements but are subject to the relevant annual reporting and announcement requirements set out in Chapter 14A of the Listing Rules.

Procurement of R&D-related Drugs and Consumables

We have historically procured R&D-related drugs and consumables (the “**R&D-related Drugs and Consumables**”) from Kelun Medicine & Trade and its subsidiaries from time to time in our ordinary course of business. R&D-related Drugs and Consumables primarily include clinical comparator drugs which are used in clinical trials to compare the efficacy of an investigational drug to the efficacy of an existing treatment and medical consumables including protective equipment and laboratory supplies. We intend to continue such procurement with Kelun Medicine & Trade after the [REDACTED] for clinical trial. On [●] 2023, our Company and Kelun Medicine & Trade entered into a framework agreement in relation to the procurement of the R&D-related Drugs and Consumables (the “**R&D-related Drugs and Consumables Framework Agreement**”), pursuant to which our Group agreed to purchase the R&D-related Drugs and Consumables from Kelun Medicine & Trade (for itself and on behalf of its subsidiaries, Kelun Medicine & Trade and its subsidiaries collectively referred to as “**Kelun Medicine & Trade Group**”).

Principal Terms

The term of the R&D-related Drugs and Consumables Framework Agreement will commence from the [REDACTED] and continue until December 31, 2025 (both days inclusive). Subject to compliance with Listing Rules and applicable laws and regulations, the R&D-related Drugs and Consumables Framework Agreement may be renewed for a further term of three years from time to time, unless either party notifies the other party to the contrary with three months’ written notice prior to the expiry of the agreement’s term. Upon renewal of the R&D-related Drugs and Consumables Framework Agreement, the parties may amend the terms of the agreement based on the then prevailing circumstances.

CONNECTED TRANSACTIONS

Pricing Policy

The prices payable by us for procuring the R&D-related Drugs and Consumables have been and will be determined through arm’s length negotiation primarily based on the production cost of the R&D-related Drugs and Consumables, the sales price to external third parties and our procurement volume, with reference to a number of factors applicable to all suppliers, including but not limited to the prevailing market price of the relevant drugs and consumables of same quality, specifications of the products, delivery capability, response time and the fees charged for historical transactions of similar nature.

The R&D-related Drugs and Consumables can be readily sourced from third-party suppliers. We have been identifying alternative suppliers for the R&D-related Drugs and Consumables and we will continue to procure the relevant R&D-related Drugs and Consumables from Kelun Medicine & Trade Group only if they are provided to our Group on normal commercial terms or better when compared with other third-party suppliers.

Reasons for and Benefits of the Transaction

In the ordinary course of our business, we need to source comparator drugs in our clinical trials to compare the efficacy of our novel drugs to the efficacy of an existing treatment, and procure consumables to facilitate our R&D activities. Kelun Medicine & Trade Group is primarily engaged in wholesale of medicines and medical consumables, which is able to source R&D-related Drugs and Consumables from various drug and consumable manufacturers that could satisfy the need of our clinical trials. During the Track Record Period, we have been procuring R&D-related Drugs and Consumables from Kelun Medicine & Trade Group from time to time, which are with high quality, stable and quick delivery at reasonable prices. To ensure continuously stable and high-efficient support of our R&D activities, our Directors are of the view that continuous procurement of the R&D-related Drugs and Consumables from Kelun Medicine & Trade Group is in the interest of our Company and our Shareholders as a whole and will be beneficial to our Group.

We believe that the risk of Kelun Medicine & Trade Group terminating the connected transactions under the R&D-related Drugs and Consumables Framework Agreement is remote as the parties under this agreement have limited termination rights and the termination would not be in the commercial interest of Kelun Medicine & Trade Group. In an unlikely event that Kelun Medicine & Trade Group terminates the connected transactions under the R&D-related Drugs and Consumables Framework Agreement with us, given these R&D-related Drugs and Consumables can be readily sourced from suppliers who are Independent Third Parties, we don’t consider such termination will materially and adversely affect our business. Accordingly, we believe that our procurement of the R&D-related Drugs and Consumables from Kelun Medicine & Trade Group does not constitute any undue reliance on it. For details, please see “Relationship with our Controlling Shareholders – Independence of Our Group from our Controlling Shareholder – Operational Independence – Research and Development.”

CONNECTED TRANSACTIONS

Corporate Governance Measures

During the ordinary and usual course of business of our Company, the procurement activities are governed by our procurement policy. When procurement of raw materials or procurement from new suppliers is necessary, we would strictly follow our internal procurement policy to select suppliers. For selecting providers for the R&D-related Drugs and Consumables, our procurement team normally requests the potential supplier to provide, among others, its industrial background and credentials and the quotations with breakdown of detailed components of the materials involved. Furthermore, our procurement team routinely monitors market price for procurement of the relevant R&D-related Drugs and Consumables necessary for our R&D activities, for benchmarking and cost control purposes.

The commercial negotiations with potential suppliers are led by our Procurement Department, which independently evaluates the terms taking into account all relevant factors as we consider necessary. A decision on whether to engage such supplier will be made purely based on commercial considerations and only if we consider it is in the best interest of our Company and the Shareholders to enter into such procurement arrangement.

Historical Amounts

The following table sets forth the historical amounts of procurement of the R&D-related Drugs and Consumables by our Group from Kelun Medicine & Trade Group for the years ended December 31, 2021 and 2022:

For the year ended December 31,		
2021		2022
	<i>(RMB in thousands)</i>	
9,838		25,605

The significant increase in historical transaction amount under the R&D-related Drugs and Consumables Framework Agreement in 2022 was primarily due to (i) the proven stable supply capacity of Kelun Medicine & Trade Group, although many other suppliers encountered certain difficulties in delivering the R&D-related Drugs and Consumables on time under unexpected circumstances in 2022; and (ii) the increased demand for comparator drugs used in clinical trials conducted in 2022.

Annual Caps and Basis of Annual Caps

The following table sets forth the proposed annual caps for the amounts payable by our Group to Kelun Medicine & Trade Group in respect of the procurement of the R&D-related Drugs and Consumables under the R&D-related Drugs and Consumables Framework Agreement:

Proposed annual cap for the year ending December 31,		
2023	2024	2025
	<i>(RMB in thousands)</i>	
20,000	40,000	30,000

CONNECTED TRANSACTIONS

The proposed annual caps are determined based on the following factors:

- (i) the unit price of the R&D-related Drugs and Consumables and the potential price fluctuation;
- (ii) the historical purchase volume of the R&D-related Drugs and Consumables by our Group from Kelun Medicine & Trade Group;
- (iii) the anticipated demand for the R&D-related Drugs and Consumables driven by the R&D progress of our product candidates for the next three years, highlighted by the demand for comparator drugs to be used in the planned pivotal trials in 2024; and
- (iv) the relevant supply capacity of Kelun Medicine & Trade Group in providing the R&D-related Drugs and Consumables.

Listing Rules Implications

As our Group is eligible for [REDACTED] on the Stock Exchange under Chapter 18A of the Listing Rules and the revenue we record during the Track Record Period was not derived from R&D, manufacturing and commercialization of novel drugs, the calculation of revenue ratio under Rule 14.07 of the Listing Rules is inappropriate to the sphere of activity of our Group, and thus we consider it inapplicable. As an alternative, we have applied a percentage ratio test based on the total expenses for R&D and general and administrative matters of our Group.

As the highest of all applicable percentage ratios (as defined in Rule 14.07 of the Listing Rules) in respect of the proposed annual caps of the R&D-related Drugs and Consumables Framework Agreement will be no less than 0.1% but will not exceed 5%, the transactions under the R&D-related Drugs and Consumables Framework Agreement are continuing connected transactions exempt from the circular (including independent financial advice) and shareholders’ approval requirements but are subject to the relevant annual reporting and announcement requirements set out in Chapter 14A of the Listing Rules.

NON-EXEMPT CONTINUING CONNECTED TRANSACTION

Licensing Agreement

Kelun Research Institute, a wholly-owned subsidiary of Kelun Pharmaceutical, as the licensor, and our Company, as the licensee, entered into a patent and technology license agreement in relation to A167 (the “**Licensing Agreement**”) on January 12, 2017, pursuant to which Kelun Research Institute agreed to grant exclusive license rights to us to globally promote and commercialize A167 (the “**Licensed Product**”).

In May 2017, Kelun Research Institute transferred the patent in relation to A167 (the “**A167 Patent**”) to the Company at nil consideration, while retaining certain non-patent technologies. To reflect (i) the licensing of the non-parent technologies by Kelun Research Institute; and (ii) the economic interests of the transferred A167 Patent and its future commercialization value, the Company and Kelun Research Institute agreed to continue the Licensing Agreement.

CONNECTED TRANSACTIONS

Principal terms

Under the Licensing Agreement, we don't need to pay any upfront payment to Kelun Research Institute. However, we need to share with Kelun Research Institute the profit derived from the sale of the Licensed Product after its commercialization (the “**Profit Sharing**”). The Profit Sharing was determined after arms' length negotiations between our Group and the Kelun Research Institute with reference to various factors, including but not limited to the costs and risk of development of the Licensed Product, expected prospects of the development and commercialization of the Licensed Product and the reasons for and benefits of the transactions contemplated under the License Agreement. The term of the Licensing Agreement commenced on the date of the agreement and continues to be in force and effect until the expiration date of the patent of the Licensed Product, being March 1, 2037. Up to the Latest Practicable Date, we hadn't paid any amount to Kelun Research Institute in connection with the Licensing Agreement as the Licensed Product has not commercialized.

Reasons for and benefits of the transaction

The License Agreement was entered into by our Group and Kelun Research Institute out of independent commercial considerations since the Kelun Research focuses its resources on the research and development of generic drugs, while our Group is committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs. It is natural and commercially beneficial for both groups to enter into the License Agreement so that both groups will be able to stick to their respective business plans and development paths. In May 2017, Kelun Research Institute transferred the A167 Patent to us at nil consideration. Both parties agreed to continue the Licensing Agreement to reflect (i) the licensing of the non-patent technologies by Kelun Research Institute to us; and (ii) the economic interests of the transferred A167 Patent and its future commercialization value. Our Directors are of the view that the Profit Sharing under the Licensing Agreement is fair and reasonable given A167 Patent was transferred by Kelun Research Institute to us at nil consideration and the Profit Sharing will only be triggered after commercialization of A167. Therefore, our role and the role of Kelun Research Institute in the arrangement under the License Agreement are complementary and beneficial to each other. As confirmed by Frost & Sullivan, the License Agreement (including the Profit Sharing contemplated thereunder) is in line with the industry prevailing practice. As such, our Directors are of the view that the License Agreement is in the interest of our Company and the Shareholders as a whole.

Corporate Governance Measures

During the ordinary and usual course of business of our Company, we review potential product licensing opportunities, including product in-licensing and out-licensing, from time to time. When potential opportunity arises, we would normally assess the advantages and development prospect of the product, market forecasts for the demand of the product, competitive landscape and regulatory requirements of the product for that market as well as the regulatory and commercial capability of the potential business partner to commercialize the product. Furthermore, our business development team routinely evaluates licensing arrangement by third parties with similar mechanism of action for deal benchmarking and for term sheet evaluation purposes.

CONNECTED TRANSACTIONS

In addition, the commercial negotiations with potential licensing partners are led by our senior management, who are not interested in the licensing and will independently evaluate the terms taking into account all relevant factors as we consider necessary. A decision on whether to enter into licensing arrangements with another company will be made purely based on commercial considerations and only if we consider it is in the best interest of our Company and the Shareholders to enter into such licensing arrangement.

Term of the License Agreement

Rule 14A.52 of the Listing Rules provides that the period for the agreement of a continuing connected transaction must not exceed three years except in special circumstances where the nature of the transaction requires a longer period. Our Directors are of the view that the nature of License Agreement requires a longer period commencing from the date of the agreement and continue to be in force until the expiration date of the patent of the Licensed Product, being March 1, 2037, on the grounds that: (i) the License Agreement allowed our Group and Kelun Research Institute to spread the risks and costs associated with the marketing and sales of the Licensed Product and to better deploy their respective resources and established capabilities to expeditiously establish an advantageous position in relevant markets. Imposing a restriction on the term of the License Agreement for a period of three years would deviate from the market prevailing practice and be contrary to the business intention of the parties; (ii) such a long-term cooperation is in the interest of our Company and the Shareholders as a whole; and (iii) as confirmed by Frost & Sullivan, the term of the License Agreement, which exceeds three years, is in line with the industry prevailing practice.

Historical Transaction Amounts

Under the Licensing Agreement, we don't need to pay any upfront payment to Kelun Research Institute. As the Licensed Product has not yet been approved for commercialization by the relevant authorities, there was no historical amount paid by our Group to the Kelun Research Institute under the License Agreement during the Track Record Period.

Caps on Future Transaction Amounts

The payment receivable by the Kelun Research Institute from us for Profit Sharing pursuant to the License Agreement will be determined in accordance with the following formula:

Sales within the PRC

Amount receivable by Kelun Research Institute under Profit Sharing = net sales revenue¹
x percentage of the profit sharing ratio²

CONNECTED TRANSACTIONS

Sales outside the PRC

Amount receivable by Kelun Research Institute under Profit Sharing = net sales revenue¹
x 6%

Notes:

1. The net sales revenue refers to the revenue generated from the sales of products excluding packing and shipping fees, relevant tax, advertising fees and commercial discounts.
2. The profit sharing rate will be no more than 4% and will be determined based on the NDA filing status of the Licensed Product as compared to that of its competitors in the market.

Taking into account the clinical trial stage of the Licensed Product as opposed to concept stage or R&D stage products, the arrangement of the Profit Sharing is fair and reasonable and in the interest of our Company and the Shareholders as a whole because (i) the Profit Sharing contemplated under the License Agreement, including the formula as stated above, was determined after arm's length negotiation between Kelun Research Institute and us and in the ordinary and usual course of the business of the two groups; (ii) we are not obliged to pay any upfront payment to Kelun Research Institute under the License Agreement. If the formula produces negative results, we would not need to pay any amount to Kelun Research Institute. As advised by Frost & Sullivan, the License Agreement and the Profit Sharing arrangements thereunder are in line with the market practice.

We have applied to the Stock Exchange for a waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules so as to allow us to set the annual caps in relation to continuing connected transactions under the License Agreement as the formula in accordance with the terms as set out in the License Agreement for the following reasons:

- (i) there was no historical amount and sufficient data for us to establish a model to estimate the future sales volume and amount for the Licensed Product as it is a newly developed drug without sufficient market data to analyze the extent of acceptance of this drug by the addressable market. It is impractical for us to accurately estimate the amount of payment to be paid under the Profit Sharing as the amount of Licensed Product and the revenue to be derived from the sale of Licensed Products depends on the actual addressable market of the product, which will in turn depend on various factors including but not limited to the acceptance by the medical community and patient access, drug pricing, reimbursement and the number of patients, all of which are beyond the control of our Group. Even if we are able to set up a projection model for estimation purpose, such a model will only present hypothetical predictions, which is not based on scientific analysis using historical data, and could be inaccurate, unreliable and even misleading;
- (ii) imposing an arbitrary cap on the potential sales volume of the Licensed Product does not demonstrate commercial reasonableness and would be counter-productive as far as the interests of the Company and our Shareholders are concerned. In the absence of a factually and mathematically reliable model to estimate the annual supply

CONNECTED TRANSACTIONS

volume of the Licensed Products, imposing an arbitrary monetary cap may become an arbitrary ceiling on the transaction amount under Profit Sharing. In addition, a fixed annual cap is not helpful to incentivize our Group to generate more revenue and profit from commercializing the Licensed Product, and will restrict business growth of our Group, which would go against the commercial objective of the Licensing Agreement. If the actual sales volume of the Licensed Product exceeds the cap, the Company would be suspended from selling the Licensed Products to the market until relevant shareholder approval of the adjusted annual caps is obtained, which will affect not only our business but also the patients who need the Licensed Product for treatment, and further affect our market recognition among the doctors and hospitals because they are not able to sustain a stable supply of the Licensed Product. As far as the transactions are on normal commercial terms or better, and the profit margin of the Licensed Product and the profit sharing percentage are commercially reasonable and in line with market standards, the interests of our Group and our Shareholders are protected, and there is no reason or benefit to impose such fixed cap;

- (iii) given most of our products are in the research and development stage, the revenue generated from the Profit Sharing may account for a sizeable portion of our total revenue before the commercialization of other drugs of our Group. Therefore, the disclosure of the annual caps in monetary terms would in effect provide Shareholders and investors as well as competitors of our Company with an indication of our estimated revenue, and may allow them to extrapolate the likely volume of the Licensed Product to be supplied and even the unit supply price of the Licensed Product. Such information is highly sensitive and would therefore put us in disadvantageous position in relation to our business operation and competition with other market players; and
- (iv) instead of setting a fixed annual cap on the Profit Sharing, if there is any material change to the percentage of the profit sharing ratio under the Profit Sharing, we will re-comply with the applicable rules under Chapter 14A of the Listing Rules, including seeking independent shareholders' approval where the case may so require, so as to further ensure the interest of our Group and our Shareholders.

The Stock Exchange [has granted] the waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules in respect of the continuing connected transactions under the License Agreement subject to the following conditions:

- (i) our Company will comply with the announcement, circular and independent Shareholder's approval requirements under Chapter 14A of the Listing Rules if there is any material change to the terms of the License Agreement;
- (ii) our Company will designate a team to execute and ensure that the transactions in relation to the License Agreement are undertaken in accordance with the terms of the License Agreements;

CONNECTED TRANSACTIONS

- (iii) our chief executive officer will use his best endeavours to supervise the compliance with the terms of the License Agreement and applicable Listing Rules requirements to the extent not waived by the Stock Exchange on a regular basis;
- (iv) the independent non-executive Directors and the auditors of the Company will review the transactions in relation to the License Agreement on an annual basis and confirm in our annual reports the matters set out in Rules 14A.55 and 14A.56 of the Listing Rules, respectively;
- (v) our Company will disclose in the document the background for entering into the License Agreement, the terms of the License Agreement, the grounds for the waiver sought and the Directors' views on the fairness and reasonableness of the transactions under the License Agreement;
- (vi) our Company will disclose in the annual report (i) the transaction amount under the Licensing Agreement during the relevant financial year; (ii) a description of the basis for calculating the fees based on the formula set out in the Licensing Agreement; and (iii) a confirmation that the transaction is in compliance with the terms of the Licensing Agreement and the relevant requirements under the Listing Rules; and
- (vii) in the event of any future amendments to the Listing Rules imposing more stringent requirements than those as at the date of this document on the above continuing connected transactions, the Company will take immediate steps to ensure compliance with such new requirements.

The waiver set out above is for a term of [three] years ending on December 31, 2025. The Company will, after taking into account, among other things, the addressable market, the drug pricing and the historical transaction amount of the relevant products, re-assess whether a further waiver is required at the expiry of such initial term.

Listing Rules Implications

Since the highest of all applicable percentage ratios in respect of the License Agreement might be 5% or more, the transactions under the License Agreement will constitute a continuing connected transaction subject to reporting, annual review, announcement, circular and independent Shareholders' approval requirements under Chapter 14A of the Listing Rules.

WAIVER APPLICATION FOR PARTIALLY EXEMPT AND NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

By virtue of Rule 14A.76(2) of the Listing Rules, each of the transactions under the sub-section "– Partially Exempt Continuing Connected Transactions" will constitute connected transactions which are subject to reporting, annual review and announcement under Chapter 14A of the Listing Rules. Each of the transactions under the sub-section "– Non-Exempt Continuing Connected Transaction" will constitute connected transactions which are subject to reporting, annual review, announcement and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

As the above partially exempt and non-exempt continuing connected transactions are expected to continue on a recurring and continuing basis, our Directors consider that compliance with the above announcement and/or independent shareholders' approval requirements would be impractical, would add unnecessary administrative costs to us and would be unduly burdensome to us.

CONNECTED TRANSACTIONS

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver to us under Rule 14A.105 of the Listing Rules from compliance with the announcement and/or independent shareholder’s approval requirements in respect of the above partially exempt and non-exempt continuing connected transactions. In addition, we confirm that we will comply with the Listing Rules in relation to the discloseable and non-exempt continuing connected transactions. In the event of any future amendments to the Listing Rules imposing more stringent requirements than those applicable as of the Latest Practicable Date on the continuing connected transactions referred to in this document, our Company will take immediate steps to ensure compliance with such new requirements within a reasonable time.

For reasons set out in the paragraph headed “– Non-exempt Continuing Connected Transaction – Licensing Agreement – Caps on Future Transaction Amounts” above, our Company has applied for, and the Stock Exchange [has granted], a waiver from strict compliance with Rule 14A.53 of the Listing Rules.

CONFIRMATION FROM OUR DIRECTORS

Our Directors (including independent non-executive Directors) are of the view that (i) the partially exempt and non-exempt continuing connected transactions set out above have been and will be entered into in the ordinary and usual course of our business on normal commercial terms or better which are fair and reasonable and in the interests of our Group and our Shareholders as a whole; (ii) the proposed monetary annual caps in respect of the partially exempt and non-exempt continuing connected transactions are fair and reasonable and in the interests of our Group and our Shareholders as a whole; and (iii) the License Agreement, notwithstanding that it has not adopted monetary annual caps, has been entered into in the ordinary and usual course of the Group’s business, is on normal commercial terms or better, and is fair and reasonable and in the interests of our Company and its Shareholders as a whole.

CONFIRMATION FROM THE JOINT SPONSORS

Having considered the above, the Joint Sponsors are of the view that (i) the aforesaid non-exempt continuing connected transactions have been entered into in the ordinary and usual course of business of the Company on normal commercial terms or better which are fair and reasonable, and in the interests of the Company and the Shareholders as a whole; (ii) the proposed monetary annual caps or alternative caps (as applicable) in respect of the partially exempt and non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and the Shareholders as a whole; and (iii) taking into consideration (a) the reasons for and benefits of entering into the Trademark Licensing Agreement and the License Agreement as set out above, (b) the confirmation from Frost & Sullivan on the terms of the Trademark Licensing Agreement and the License Agreement, which exceeds three years, is in line with the industry prevailing practice, and (c) the fact that the relevant arrangements were negotiated on an arm’s length basis and in accordance with the corporate governance measures of the Company as set forth above, it is reasonable for the Trademark Licensing Agreement and the License Agreement to be entered into for a term as set out above, and it is normal business practice for agreements of this type to be of such duration.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board consists of 11 Directors, comprising two executive Directors, five non-executive Directors and four independent non-executive Directors:

Name	Age	Positions	Roles and Responsibilities	Date of Joining the Group	Date of appointment as a Director
Mr. LIU Gexin (劉革新) ^{Note (1)}	72	Chairman of the Board and non-executive Director	Overseeing the management and strategic development of the Group	November 22, 2016	November 22, 2016
Dr. GE Junyou (葛均友)	50	Executive Director and general manager	Overall corporate and business strategies of our Group and making key business and operational decisions of our Group	February 8, 2021	February 25, 2022
Dr. WANG Jingyi (王晶翼)	62	Executive Director	Overall strategic planning and development of the Group	November 22, 2016	November 22, 2016
Mr. LIU Sichuan (劉思川) ^{Note (1)}	39	Non-executive Director	Overseeing the management and strategic development of the Group	November 22, 2016	November 22, 2016
Mr. FENG Hao (馮昊)	43	Non-executive Director	Overseeing the management and strategic development of the Group	February 12, 2021	February 12, 2021
Mr. ZENG Xuebo (曾學波)	38	Non-executive Director	Overseeing the management and strategic development of the Group	July 30, 2022	July 30, 2022

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Positions	Roles and Responsibilities	Date of Joining the Group	Date of appointment as a Director
Mr. LI Dongfang (李東方)	35	Non-executive Director	Overseeing the management and strategic development of the Group	February 25, 2022	February 25, 2022
Dr. ZHENG Qiang (鄭強)	62	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	February 15, 2023 ^{Note (2)}	February 15, 2023 ^{Note (2)}
Dr. TU Wenwei (涂文偉)	56	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	February 15, 2023 ^{Note (2)}	February 15, 2023 ^{Note (2)}
Dr. JIN Jinping (金錦萍)	50	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	February 15, 2023 ^{Note (2)}	February 15, 2023 ^{Note (2)}
Dr. LI Yuedong (李越冬)	46	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	February 15, 2023 ^{Note (2)}	February 15, 2023 ^{Note (2)}

Notes:

- (1) Mr. LIU Sichuan is the son of Mr. LIU Gexin.
- (2) The appointment will become effective upon the [REDACTED].

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Chairman of the Board and non-executive Director

Mr. LIU Gexin (劉革新), aged 72, was appointed as a Director and the chairman of the Board in November 2016 and March 2022, respectively. He was redesignated as our non-executive Director on February 15, 2023. He is mainly responsible for overseeing the management and strategic development of the Group.

Mr. Liu is the founder of Kelun Pharmaceutical and has served as the chairman of Kelun Pharmaceutical since its establishment. From November 2020 to October 2022, he served as a director of Kelun Research Institute. In addition, Mr. Liu currently has also held positions in a number of subsidiaries of Kelun Group, including (i) the chairman of Sichuan Kelun Industry Group Co., Ltd. (四川科倫實業集團有限公司); (ii) the chairman of Chengdu Qingshan Likang Pharmaceutical Co., Ltd. (成都青山利康藥業有限公司); (iii) the chairman of Yili Chuanning Biotechnology Co., Ltd. (伊犁川寧生物技術股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 301301); and (iv) a director of Chengdu Huaxi Clinical Research Co., Ltd. (成都華西臨床研究中心有限公司).

Mr. Liu obtained his master’s degree in cardiovascular pharmacology from Chongqing Medical College (重慶醫學院) (currently known as Chongqing Medical University (重慶醫科大學)) in China in June 1984. Mr. Liu also obtained his another master’s degree in political economics from Southwest Normal University (西南師範大學) (currently known as Southwest University (西南大學)) in China in July 2003. Mr. Liu has received a series of awards and recognition, including (i) the National Model Worker (全國勞動模範) by The State Council, PRC (中華人民共和國國務院) in May 2005 and (ii) the Second Prize of National Science and Technology Progress Award (國家科技進步二等獎) by The State Council, PRC (中華人民共和國國務院) in December 2014.

Executive Director

Dr. GE Junyou (葛均友), aged 50, was appointed as a Director in February 2022. He was redesignated as our executive Director on February 15, 2023. Dr. Ge was appointed as the chief operation officer of the Company in February 2021 and the general manager of the Company in March 2022. He is mainly responsible for overall corporate and business strategies of our Group and making key business and operational decisions of our Group. Mr. Ge has also served as a director of KLUS PHARMA since December 1, 2021, an executive director of Sichuan Konas since November 17, 2021, and an executive director and a manager of Kelun-Biotech Research Center since March 30, 2023.

From July 1994 to December 1997, Dr. Ge served as a production and R&D officer of Shanghai Yan’an Pharmaceutical Factory (上海延安製藥廠). From January 1998 to April 2000, he served as a deputy manager of the technical department of Shanghai Hengshoutang Pharmaceutical Co., Ltd. (上海恒壽堂藥業有限公司). From April 2000 to January 2004, he served as a GMP compliance manager of Boehringer Ingelheim Pharmaceutical Co., Ltd. (Shanghai) (上海勃林格殷格翰藥業公司). From January 2004 to January 2006, he served as an assistant to general manager of Zhejiang Hisun Pharmaceutical Co., Ltd. (浙江海正藥業股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600267). From

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

January 2006 to May 2007, he served as a quality manager of Ratiopharm GmbH. Dr. Ge joined Kelun Pharmaceutical in June 2007 and served as a deputy general manager from July 2009 to February 2021, where he was mainly responsible for leading the quality management of Kelun Group. Prior to formally joining our Group as our chief operating officer in February 2021, by virtue of his position and responsibilities as a deputy general manager of Kelun Pharmaceutical, Dr. Ge has been familiar with our Group’s business and operations and had been in charge of the quality control of Kelun Group (including that of our Company) since 2018. Dr. Ge led the establishment and construction of GMP system of our Group and has been involved in the production quality management of our Group, including the quality control of our production management department, production quality department, equipment engineering department, and warehouse and logistics department. He also participated in our Group’s CMC activities, team management and building, promotion of production projects, and decision-making for facility construction and procurement.

Dr. Ge obtained his bachelor’s degree in pharmacy from Shanghai Medical School (上海醫科大學) (currently known as Shanghai Medical College Fudan University (復旦大學上海醫學院)) in China in July 1994. He obtained his master’s degree in pharmaceutical engineering from East China University of Science and Technology (華東理工大學) through on-the-job learning in China in November 2008. He also obtained his doctoral degree in biology and medicine from Fudan University (復旦大學) in China in January 2017. Dr. Ge has received a series of awards and recognition including (i) the Second Prize of Hunan Provincial Technology Invention Award (湖南省技術發明獎二等獎) by the People’s Government of Hunan Province (湖南省人民政府) in February 2017 and (ii) the tenth batch of outstanding experts with outstanding contributions in Chengdu (第十批成都市有突出貢獻的優秀專家) by Chengdu Committee of the CPC and the People’s Government of Chengdu (中共成都市委、成都市人民政府) in February 2018.

Dr. WANG Jingyi (王晶翼), aged 62, was appointed as a Director of our Company in November 2016 and was redesignated as an executive Director on February 15, 2023. Dr. Wang had been serving as the general manager of our Company and ceased to act as the general manager in March 2022. He is mainly responsible for the overall strategic planning and development of the Group.

From December 1999 to March 2001, Dr. Wang served as a research assistant professor in medicine of University of Arkansas for Medical Sciences. He formerly served as a vice general manager of QILU Pharmaceutical Co., Ltd. (齊魯製藥有限公司) and the president of QILU Pharmaceutical and Drug Research Institute (齊魯製藥藥物研究院). From November 2012 to February 2021, Dr. Wang served as a director of Kelun Pharmaceutical.

Dr. Wang is currently one of the editorial board members of China Journal of New Drugs (《中國新藥雜誌》), an evaluation expert for national science and technology awards (國家科學技術獎勵) and major national science and technology projects for major new drug creation (重大新藥創製國家科技重大專項). Dr. Wang has also been awarded the second prize of National Science and Technology Progress Award (國家科學技術進步二等獎) by The State Council, PRC (中華人民共和國國務院) for two times in recent years.

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Dr. Wang obtained his bachelor’s degree in medical medicine from China Medical University (中國醫科大學) in China in August 1983. He obtained his master’s degree and doctoral degree in immunology and medical molecular virology from The Fourth Military Medical University (解放軍第四軍醫大學) in China in November 1988 and July 1991, respectively.

Non-executive Director

Mr. LIU Sichuan (劉思川), aged 39, was appointed as a Director in November 2016. He was redesignated as our non-executive Director on February 15, 2023. He is mainly responsible for overseeing the management and strategic development of the Group.

Mr. Liu joined Kelun Pharmaceutical and served as the assistant of chairman in 2007. He has been serving as a director of Kelun Pharmaceutical since May 2009 and general manager of Kelun Pharmaceutical since September 2015. Currently he has also held positions in a number of subsidiaries of Kelun Group, including (i) a director of Chengdu Qingshan Likang Pharmaceutical Co., Ltd. (成都青山利康藥業有限公司) since June 2012; (ii) a manager and executive director of Chengdu Kelun Chuaicai Enterprise Management Co., Ltd (成都科倫川智企業管理有限公司) since May 2020; (iii) a director of Yili Chuanning Biotechnology Co., Ltd. (伊犁川寧生物技術股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 301301), since June 2020; (iv) a director of Sichuan Kelun Industry Group Co., Ltd. (四川科倫實業集團有限公司) since September 2021; and (v) a manager and executive director of Chengdu Kelun Jingchuan Technology Co., Ltd. (成都科倫晶川科技有限公司) since November 2021.

Mr. Liu obtained his master’s degree in international business from the University of Leeds in the United Kingdom in August 2007. Mr. Liu has received a series of awards and recognition including the National Advanced Individual in Fighting the COVID-19 (全國抗擊新冠肺炎疫情先進個人) by CPC Central Committee, The State Council, PRC and the Military Commission of the CPC Central Committee (黨中央、中華人民共和國國務院、中央軍委) in September 2020.

Mr. FENG Hao (馮昊), aged 43, was appointed as a Director in February 2021. He was redesignated as our non-executive Director on February 15, 2023. He is mainly responsible for overseeing the management and strategic development of the Group.

Mr. Feng has been serving as: (i) a deputy general manager and secretary of board of directors of Kelun Pharmaceutical since April 2014; and (ii) a non-executive director of SSY Group Limited (石四藥集團有限公司), a company listed on the Stock Exchange (stock code: 02005) since November 2017.

From July 2002 to August 2003, Mr. Feng served as a tutor at the School of Economics at Huazhong University of Science and Technology (華中科技大學). From December 2004 to January 2005, Mr. Feng served as an analyst at the Actuarial Division of Taiping Life Insurance Company Limited. From December 2005 to December 2006, he served as an actuarial advisory consultant at Watson Wyatt Consultancy (Shanghai) Ltd. From January 2007 to August 2007, he served as a senior manager at the investment banking division of Ping An Securities Limited. From September 2007 to January 2014, he served as a business director at the investment banking division of Sinolink Securities Co. Ltd.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Feng obtained his master’s degree in financial mathematics from Heriot-Watt University in the United Kingdom in November 2005. Mr. Feng has received a series of awards and recognition including the 2022 5A Rating for Duty Performance of Board Secretary of Listed Companies (2022上市公司董事會秘書履職5A評級) by China Association for Public Companies (中國上市公司協會) on December 12, 2022.

Mr. ZENG Xuebo (曾學波), aged 38, was appointed as a Director in July 2022. He was redesignated as our non-executive Director on February 15, 2023. He is mainly responsible for overseeing the management and strategic development of the Group.

Formerly he served as a manager and was then promoted as a director (總監) of Shenzhen Zhongyi Yingtai Venture Capital Co., Ltd. (深圳中逸盈泰創業投資有限公司). From June 2015 to July 2016, he served as a deputy director (副總監) of Shenzhen Investment Holdings Donghai Investment Co., Ltd. (深圳投控東海投資有限公司). From August 2016 to July 2019, he served as a director (總監) and was then promoted as a vice president of Aiqi Venture Capital Management (Shenzhen) Co., Ltd. (愛奇創業投資管理(深圳)有限公司). He has served as a vice president of Hexie Zhuorui (Zhuhai) Investment Management Co., Ltd. (和諧卓睿(珠海)投資管理有限公司) since November 2020.

Currently he also holds positions in various companies, including (i) a director of Shandong Bestcomm Pharmaceutical Company Limited (山東百諾醫藥股份有限公司); (ii) a director of Hang Zhou Sciwind Biosciences Co., Ltd. (杭州先為達生物科技有限公司); (iii) a director of Shanghai Model Organisms Center, Inc. (上海南方模式生物科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688265), since September 2022; and (iv) a director of Chiral Quest (Suzhou) Co., Ltd. (凱瑞斯德生化(蘇州)有限公司).

Mr. Zeng obtained his bachelor’s degree in pharmacy from Qinghai Minzu University (青海民族大學) in China in July 2009.

Mr. LI Dongfang (李東方), aged 35, was appointed as a Director in February 2022. He was redesignated as our non-executive Director on February 15, 2023. He is mainly responsible for overseeing the management and strategic development of the Group.

From August 2011 to March 2015, Mr. Li served as an analyst of Goldman Sachs (Asia) L.L.C. He has been serving as an executive director of SDIC Investment Management Co., Ltd. (國投招商投資管理有限公司) since August 2015, where he is responsible for equity investment.

Mr. Li obtained his bachelor’s degree and master’s degree in electronic commerce and finance from University of International Business and Economics (對外經濟貿易大學) in China in July 2009 and July 2011, respectively. He has been a Chartered Financial Analyst since June 2015.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Independent Non-executive Directors

Dr. ZHENG Qiang (鄭強), aged 62, was appointed as an independent non-executive Director on February 15, 2023 with effect from the [REDACTED]. He is mainly responsible for supervising and providing independent advice on the operation and management of our Group.

Dr. Zheng joined the Peking University (北京大學) in 2005, and he has been serving as a professor and doctoral supervisor in industrial engineering and management in Peking University (北京大學).

Dr. Zheng obtained his bachelor’s degree in physics from Peking University (北京大學) in China in July 1983. Dr. Zheng obtained his master’s degree in physics from Graduate School of Chinese Academy of Sciences (中國科學院研究生院) (currently known as University of Chinese Academy of Sciences (中國科學院大學) in China in August 1986. He also obtained his doctoral degree in physics from Temple University in the United States in June 1989.

Dr. TU Wenwei (涂文偉), aged 56, as appointed as an independent non-executive Director on February 15, 2023 with effect from the [REDACTED]. He is mainly responsible for supervising and providing independent advice on the operation and management of our Group.

Dr. Tu successively served as a lecturer and attending doctor at the department of paediatrics of Children’s Hospital, Chongqing Medical University (重慶醫科大學附屬兒童醫院) and a postdoctoral researcher fellow in the department of pediatrics at the Stanford University School of Medicine in the United States before 2006. Dr. Tu has served as a professor in the department of paediatrics & adolescent medicine, Li Ka Shing Faculty of Medicine at The University of Hong Kong (the “HKU”) since June 2015. Dr. Tu also held various positions, such as the assistant dean of the Li Ka Shing Faculty of Medicine since October 2011 and an associate professor since June 2009 at the department of paediatrics & adolescent medicine since joining HKU in 2006.

Dr. Tu obtained his bachelor’s and master’s degrees in medicine sciences from Chongqing Medical University (重慶醫科大學) in the PRC in July 1989 and December 1992, respectively. He obtained his doctoral degree in philosophy from HKU in December 1999. Dr. Tu has received a series of awards including several Prize of Science and Technology Progress (科技進步獎). He was also recognized as a Changjiang scholar chair professor in pediatrics (長江學者講座教授(兒科)) by Ministry of Education of PRC (中華人民共和國教育部) in April 2016.

Dr. JIN Jinping (金錦萍), aged 50, as appointed as an independent non-executive Director on February 15, 2023 with effect from the [REDACTED]. She is mainly responsible for supervising and providing independent advice on the operation and management of our Group.

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Dr. Jin serves as an associate professor in the Law School, Peking University (北京大學). She has been serving as an independent director of Beijing Oriental Jicheng Co., Ltd. (北京東方中科集成科技股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002819), since July 2018 and an independent director of China Automotive Engineering Research Institute Co., Ltd. (中國汽車工程研究院股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 601965), since January 2020.

Dr. Jin obtained her bachelor’s degree, master’s degree and doctoral degree in law from Peking University (北京大學) in China in July 1995, July 2001 and June 2004, respectively.

Dr. LI Yuedong (李越冬), aged 46, was appointed as an independent non-executive Director on February 15, 2023 with effect from the [REDACTED]. She is mainly responsible for supervising and providing independent advice on the operation and management of our Group.

Dr. Li joined the Southwestern University of Finance and Economics (西南財經大學) in 2011 and she has been serving as a doctoral supervisor in Auditing in Southwestern University of Finance and Economics (西南財經大學) since January. She has been serving as (i) an independent director of Chengdu Leejun Industrial Co., Ltd. (成都利君實業股份有限公司) since July 2021, a company listed on the Shenzhen Stock Exchange (stock code: 002651); (ii) an independent director of Chengdu Sino Microelectronics Technology Co., Ltd. (成都華微電子科技股份有限公司) since September 2021; (iii) an independent director of Ya’an Baitu High Tech Materials Co., Ltd. (雅安百圖高新材料股份有限公司) since September 2022; (iv) an independent director of Chengdu Zhimingda Electronics Co., Ltd. (成都智明達電子股份有限公司), a company listed on Shanghai Stock Exchange (stock code: 688636), since November 2022; and (v) an independent director of Chengdu Shengbang Seals Co., Ltd. (成都盛幫密封件股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 301233), since November 2022. In addition, Dr. Li also served as (i) an independent director of Kelun Group from June 2015 to June 2021; (ii) an independent director of Chengdu Hi-Tech Development Co., Ltd. (成都高新發展股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 000628) from June 2015 to June 2022; (iii) an independent director of Sichuan Fengsheng Paper Technology Co., Ltd. (四川鳳生紙業科技股份有限公司) from December 2019 to December 2022; and (iv) an independent director of Sichuan Neautus Traditional Chinese Medicine Co., Ltd. (四川新荷花中藥飲片股份有限公司) from January 2020 to February 2023.

Dr. Li obtained her bachelor’s degree in economics from Chongqing Business College (重慶商學院) (currently known as Chongqing Technology and Business University (重慶工商大學)) in China in July 2000. Dr. Li obtained her master’s degree in accountancy from Georgia College & State University in the United States in May 2004. She also obtained her doctoral degree in business administration from Southwestern University of Finance and Economics (西南財經大學) in China in January 2011. Dr Li was certified as a public accountant by the Guam Board of Accountancy in August 2015. She also completed audit training course in the United Nations in June 2020. Dr. Li has received a series of awards and recognition. She was recognized as an internationalized high-end accounting talent (國際化高端會計人才) by Ministry of Finance of the PRC (中國財政部) in December 2021.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF SUPERVISORS

The Board of Supervisors comprises six members. The following table sets out information in respect of the Supervisors of our Company:

Name	Age	Positions	Roles and Responsibilities	Date of Joining the Group	Date of appointment as a Supervisor
Mr. LAI Degui (賴德貴)	52	Chairman of the Board of Supervisors and Supervisor	Supervising the performance of duties by Directors and senior management	February 12, 2021	February 12, 2021
Ms. LIAO Yihong (廖益虹)	43	Supervisor	Supervising the performance of duties by Directors and senior management	February 25, 2022	February 25, 2022
Mr. WAN Peng (萬鵬)	47	Supervisor	Supervising the performance of duties by Directors and senior management	February 12, 2021	February 12, 2021
Dr. SONG Hongmei (宋宏梅)	40	Supervisor	Supervising the performance of duties by Directors and senior management	May 18, 2019	March 1, 2021
Ms. YANG Qiuyan (楊秋艷)	38	Supervisor	Supervising the performance of duties by Directors and senior management	August 18, 2017	March 29, 2022
Dr. QING Yan (卿燕)	39	Supervisor	Supervising the performance of duties by Directors and senior management	January 1, 2021	March 29, 2022

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. LAI Degui (賴德貴), aged 52, was appointed as the chairman of the Board of Supervisors and a Supervisor in February 2021. He is mainly responsible for supervising the performance of duties by Directors and senior management.

Mr. Lai has been served as (i) a deputy general manager and financial director of Kelun Pharmaceutical since October 2014; (ii) a supervisor of Chengdu Kelun Chuanzhi Enterprise Management Co., Ltd. (成都科倫川智企業管理有限公司) since May 2020; (iii) an executive director of Zhejiang Keyun IOT Technology Co., Ltd. (浙江科運物聯科技有限公司) since December 2020; (iv) an executive director and general manager of Shanxi Keyun IOT Technology Co., Ltd. (山西科運物聯科技有限公司) since May 2021; and (v) an executive director and general manager of (四川科誌物聯科技有限公司) since October 2021.

Mr. Lai received a diploma of accounting from Southwestern University of Finance and Economics (西南財經大學) through on-the-job learning in January 2013.

Ms. LIAO Yihong (廖益虹), aged 43, was appointed as a Supervisor in February 2022. She is mainly responsible for supervising the performance of duties by Directors and senior management.

Ms. Liao has served as a supervisor of Kelun Pharmaceutical and other subsidiaries of Kelun Group. Ms. Liao served as the chief director of audit of Kelun Pharmaceutical from December 2014 to June 2021, and served as the chief director of procurement from July 2021 to March 2022. Ms. Liao was promoted as a deputy general manager of Kelun Pharmaceutical in April 2022.

From August 2002 to September 2006, Ms. Liao served as a senior auditor in Shenzhen branch of PricewaterhouseCoopers Zhongtian Certified Public Accountants (special general partnership) (普華永道中天會計師事務所(特殊普通合夥)). From September 2006 to November 2014, she served as an audit manager in the Chengdu branch of KPMG Consulting (China) Co., Ltd. (畢馬威企業諮詢(中國)有限公司).

Ms. Liao obtained her bachelor’s degree in accounting from Guangdong University of Foreign Studies (廣東外語外貿大學) in China in June 2002. She obtained her master’s degree in accounting from Tsinghua University (清華大學) through on-the-job learning in China in June 2021.

Mr. WAN Peng (萬鵬), aged 47, was appointed as a Supervisor in February 2021. He is mainly responsible for supervising the performance of duties by Directors and senior management.

Mr. Wan has served as the general legal counsel and a non-employee representative supervisor of Kelun Pharmaceutical since December 2007 and March 2015, respectively. He worked as one legal counsel in the Sichuan Kelun Pharmaceutical Factory (四川科倫大藥廠), the predecessor of Kelun Pharmaceutical, in November 2001.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Wan obtained his on-the job master of business administration from Sichuan University of Business Administration (四川省工商管理學院) in China in July 2005.

Dr. SONG Hongmei (宋宏梅), aged 40, was appointed as a Supervisor in March 2021. She is mainly responsible for supervising the performance of duties by Directors and senior management. Dr. Song joined our Group in May 2019 and has served as our vice president of R&D.

From November 2012 to December 2014, Dr. Song successively served as a team leader of biological R&D and an assistant director of biology at HitGen Inc. (成都先導藥物開發有限公司), where she was mainly responsible for hit screening and activity evaluation, and project and team management. From January 2015 to November 2017, she successively served as a project manager and a vice minister of pharmacology department of Kelun Research Institute. From December 2017 to May 2019, she served as the head of innovation center of Kelun Research Institute.

Dr. Song obtained her bachelor’s degree in bioscience from Sichuan Agricultural University (四川農業大學) in China in June 2005. She obtained her master’s degree in biochemistry and molecular biology from Sichuan University (四川大學) in China in June 2010. She obtained her doctoral degree in biomedical engineering from Sichuan University (四川大學) in China in December 2012.

Ms. YANG Qiuyan (楊秋艷), aged 38, joined our Company as the head of production management department in August 2017 and was appointed as a Supervisor in March 2022. She is mainly responsible for supervising the performance of duties by Directors and senior management.

She served as a project manager of the microbiology research team and a deputy minister of biopharmaceuticals of Kelun Research Institute from July 2010 to June 2013 and from June 2013 to August 2017, respectively.

Ms. Yang obtained her bachelor’s and master’s degree in biological engineering and biochemical engineering from Sichuan University (四川大學) in China in July 2007 and June 2010, respectively.

Dr. QING Yan (卿燕), aged 39, joined our Company as a vice president of the clinical research center in January 2021 and was appointed as a Supervisor in March 2022. She is mainly responsible for supervising the performance of duties by Directors and senior management.

From November 2012 to December 2020, she was a director of the medical information center of Kelun Research Institute, where she was mainly responsible for innovative small molecules, imitation projects, pipeline construction.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Qing obtained her bachelor’s and master’s in clinical medicine from Tongji Medical College of Huazhong University of Science and Technology (華中科技大學同濟醫學院) in China in June 2007 and June 2009, respectively. Dr. Qing obtained her doctoral degree in occupational hygiene and environmental hygiene (direction of toxicology) from Tongji Medical College of Huazhong University of Science and Technology (華中科技大學同濟醫學院) in China in June 2012.

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The following table sets out information in respect of the senior management members of our Company:

Name	Age	Positions	Roles and Responsibilities	Date of Joining the Group	Date of appointment as a senior management
Dr. GE Junyou (葛均友)	50	Executive Director and general manager	Overall corporate and business strategies of our Group and making key business and operational decisions of our Group	February 8, 2021	February 8, 2021
Mr. FENG Yi (馮毅)	58	Deputy general manager, chief strategy officer and senior vice president	Management of strategic planning of R&D and clinical development of our Group	December 1, 2020	December 1, 2020
Dr. ZHANG Yiwei (張一偉)	68	Deputy general manager	Management of manufacturing, quality analysis and control of our Group	January 9, 2018	January 9, 2018
Dr. TAN Xiangyang (譚向陽)	61	Deputy general manager and chief scientific officer	Management of preclinical research and business development of our Group	July 5, 2021	July 5, 2021
Dr. JIN Xiaoping (金小平)	46	Deputy general manager and chief medical officer	Management of clinical development of our Group	September 6, 2021	September 6, 2021

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Positions	Roles and Responsibilities	Date of Joining the Group	Date of appointment as a senior management
Mr. ZHOU Zejian (周澤劍)	41	Chief financial officer and the secretary of the Board	Management of finance, capital market and securities affairs of our Group	February 25, 2022	August 17, 2022
Mr. GUO Yong (郭永)	53	Deputy general manager and chief commercial officer	Management of sales, marketing, medical affairs and commercial operations of our Group	May 12, 2023	May 12, 2023

Dr. GE Junyou (葛均友), aged 50, is our executive Director and general manager. For details of his biography, please refer to the paragraph headed “– Board of Directors – Executive Director” in this section.

Mr. FENG Yi (馮毅), aged 58, was appointed as our deputy general manager and chief strategy officer in March 2021. He joined our Group as a senior vice president in December 2020. He is mainly responsible for the management of strategic planning of R&D and clinical development of our Group.

Mr. Feng formerly served as an assistant of the director of Center of Drug Evaluation, NMPA (國家藥品監督管理局藥品審評中心). From February 2014 to December 2015, he served as a senior consultant at China Office of Covington & Burling Law Firm (美國科文頓•柏靈律師事務所中國代表處), where he was mainly responsible for drug regulations. From January 2016 to August 2018, he served as the president of Greater China of Fountain Pharmaceuticals Co., Ltd. (方恩醫藥有限公司) (currently known as Clinchoice Inc. (昆翎醫藥)), where he was mainly responsible for leading and managing company. From November 2018 to November 2020, he served as senior vice dean and chief strategy officer of Kelun Research Institute.

Mr. Feng obtained his bachelor’s degree in aviation medicine from The Fourth Military Medical University of the Chinese People’s Liberation Army (中國人民解放軍第四軍醫大學) in China in July 1987. He obtained his master’s degree in radio medicine from Chinese People’s Liberation Army Academy of Military Medical Sciences (中國人民解放軍軍事醫學科學院) in China in July 1996. He was recognized as the model staff (工作標兵) by Center for Drug Evaluation, Ministry of Health, PRC (中華人民衛生部藥品審評中心) in January 2001.

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Dr. ZHANG Yiwei (張一偉), aged 68, was appointed as our deputy general manager in March 2022. He joined our Group in January 2018 as the director of quality control, and was promoted to senior director in March 2020. He is mainly responsible for the management of manufacturing, quality analysis and control of our Group.

From October 1990 to August 1991, Dr. Zhang was a visiting scientist of Department of Pure and Applied Biology, The University of Leeds. From August 1995 to May 2007, he served as a postdoctoral fellow and associate researcher of Department of Pathology, Albert Einstein College of Medicine. From June 2007 to October 2008, he served as a quality control scientist of ImClone System, Inc., a company focusing on biopharmaceuticals, where he was mainly responsible for quality control of biomacromolecule drugs. From November 2008 to December 2017, he served as a senior scientist of Eli Lilly and Company, a pharmaceutical company listed on the New York Stock Exchange (stock code: LLY), where he was mainly responsible for quality control and technology development of biomacromolecule drugs.

Dr. Zhang obtained his bachelor’ degree in medicine from Chongqing Medical College (重慶醫學院) (currently known as Chongqing Medical University (重慶醫科大學)) in China in July 1984. He obtained his doctoral degree in theoretical and applied biology from University of Leeds in the United Kingdom in October 1995. Dr. Zhang was awarded the first prize of academy of science and technology (院科技壹等獎) by Sichuan Academy of Medical Sciences, PRC (中國四川省醫學科學院) in December 1989 and the third prize of Sichuan Science and Technology Progress Award in 1989 (1989年度四川省科學技術進步獎三等獎) by the People’ Government of Sichuan Province (四川省人民政府) in April 1990.

Dr. TAN Xiangyang (譚向陽), aged 61, was appointed as our deputy general manager and chief scientific officer of biologics’ research and development in July 2021. He is mainly responsible for the management of preclinical research and business development of our Group.

From June 1990 to December 1992, he served as a researcher of Wuhan Institute of Biological Products, Ministry of Health (衛生部武漢生物製品研究所). From July 1995 to June 1996, he served as a postdoctoral researcher of Harvard Medical School. From January 1998 to January 2008, he served as a principal scientist of Wyeth, LLC. From January 2008 to January 2009, he served as a principal scientist of Pfizer Inc., a company listed on the New York Stock Exchange (stock code: PFE). From February 2009 to November 2015, he served as a principal scientist of Biogen Inc., a company listed on the NASDAQ (stock code: BIIB). From January 2016 to July 2017, he served as a department head of Apbro Corporation, a company listed on the NASDAQ (stock code: ABP). From July 2017 to May 2019, he served as a vice president of Harbour BioMed Shanghai Co., Led. (和鉑醫藥(上海)有限責任公司), a subsidiary of HBM Holdings Limited (和鉑醫藥控股有限公司), a company listed on the Stock Exchange (stock code: 02142). From August 2019 to February 2021, he worked in 4B Technologies (Suzhou) Co., Ltd. (福貝生物科技(蘇州)公司) with his last position as a vice president of the R&D department. From March 2021 to July 2021, he served as a senior vice president of Duality Biologics (Suzhou) Co., Ltd. (映恩生物製藥(蘇州)有限公司), where he was mainly responsible for formulation and implementation of the technology platform for preclinical innovative drug.

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Dr. Tan obtained his bachelor’s degree in clinical medicine from Harbin Medical University (哈爾濱醫科大學) in China in August 1983. He obtained his master’s degree in microbiology and immunology from Wuhan Institute of Biological Products (衛生部武漢生物製品研究所) in China in December 1988. He obtained his doctoral degree in cell and molecular biology from Manchester Metropolitan University in the United Kingdom in November 2007.

Dr. JIN Xiaoping (金小平), aged 46, was appointed as our deputy general manager and chief medical officer in September 2021. He is mainly responsible for the management of clinical development of our Group.

From July 2005 to June 2014, he served as the staff biostatistician of a pharmaceutical company Daiichi Sankyo Inc. (第一三共株式會社) and participated in the clinical studies of new oncological medicine indications. He then served as the scientific director of pharmaceutical company AstraZeneca Biopharmaceutical Company, a company listed on the London Stock Exchange (stock code: AZN), OMX Nordic Exchange (currently known as NASDAQ OMX Group) (stock code: AZN) and New York Stock Exchange (stock code: AZN) from June 2014 to April 2017, and was responsible for setting clinical trial strategies to identify indications, designing clinical trials, managing clinical trials and analyzing relevant clinical data. He joined the group of Akeso, Inc. (“**Akeso**”), a company listed on the Stock Exchange (stock code: 09926) as a vice president and the head of clinical development in May 2017, further promoted as senior vice president in 2020, where he was mainly responsible for clinical science and development, and left Akeso in August 2021.

Dr. Jin obtained his bachelor’s degree in chemistry from Nanjing University (南京大學) in China in July 1997. He obtained his master’s degree in statistics in Washington State University in the United States in August 2001. He obtained his doctoral degree in biostatistics from School of Public Health, University of Minnesota in the United States in June 2005.

Mr. ZHOU Zejian (周澤劍), aged 41, was appointed as the chief financial officer of our Company and the secretary of the Board in August 2022. He is mainly responsible for the management of finance, capital market and securities affairs of our Group. From February 2022 to June 2022, he served as a non-executive Director of our Company, which was designated by IDG Capital, a Pre-[**REDACTED**] investor of our Company.

From November 2017 to July 2022, Mr. Zhou served as a managing director of IDG Capital, where he was mainly responsible for investment. From April 2014 to November 2017, he served as an executive director of Goldman Sachs Gao Hua Securities Company Limited (高盛高華證券有限責任公司). Prior to that, he successively worked in China International Capital Corporation Limited (中國國際金融股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 601995) and the Stock Exchange (stock code: 03908) and J.P. Morgan First Capital Securities Co., Ltd. (第一創業摩根大通證券有限責任公司).

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Mr. Zhou obtained his bachelor’s degree in financial management from Renmin University (中國人民大學) in China in July 2004. He obtained his master’s degree in finance from Renmin University (中國人民大學) in January 2007.

Mr. GUO Yong (郭永), aged 53, was appointed as our deputy general manager and chief commercial officer in May 2023. He is mainly responsible for the management of sales, marketing, medical affairs and commercial operations of our Group.

From May 1998 to April 2001, he successively served as sales representative and product executive of Eli Lilly Asia Inc (美國禮來亞洲公司). From May 2003 to November 2009, he successively served as a senior product manager, market manager and associate market director of Wyeth Pharmaceutical Co., Ltd. (惠氏製藥有限公司). From November 2009 to December 2010, he served as a north China sales director of vaccine of GlaxoSmithKline (China) Investment Company Ltd (葛蘭素史克(中國)投資有限公司). From December 2010 to October 2014, he served as a vice president of Shanghai Roche Pharmaceutical Ltd. (上海羅氏製藥有限公司). From November 2014 to December 2017, he successively held several positions in Eisai China Inc. (衛材中國製藥有限公司) with his last position as a vice president. From January 2018 to January 2021, he served as a vice president and deputy global brand lead in Eisai Inc. in the United States. From February 2021 to October 2022, he served as the chief commercial officer of Everest Medicines Limited (雲頂新耀有限公司), a company listed on the Stock Exchange (stock code: 01952).

Mr. Guo obtained his bachelor’s degree in clinical medicine from Fourth Military University (解放軍第四軍醫大學) in China in July 1994. He also obtained his master’s degree in business administration from China Europe International Business School (中歐國際工商學院) in October 2011.

Save as disclosed above, none of our Directors, Supervisors or senior management members 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 preceding the Latest Practicable Date.

As of the Latest Practicable Date and save as disclosed above, (i) none of the Directors, Supervisors or members of the senior management of our Company is related to any other Directors, Supervisors and members of the senior management, and (ii) there is no additional matter with respect to the appointment of the Directors or Supervisors that needs to be brought to the attention of the Shareholders.

Other information required to be disclosed under Rule 13.51(2)(h) to (v) of the Listing Rules

Mr. LIU Gexin (劉革新) (“**Mr. Liu**”) held positions in the following entities, each of which had its business license revoked as a result of failure to conduct annual inspection as required under the relevant PRC laws and regulations: (i) executive director and legal representative of Chengdu Longshengkang Pharmaceutical Co., Ltd. (成都隆盛康藥業有限公

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司), (ii) legal representative of Sichuan Kelun Industry Co., Ltd. (四川科倫實業有限責任公司), and (iii) director (負責人) of Sales Department of Sichuan Kelun Pharmaceutical Factory (四川科倫大藥廠銷售部), a joint stock cooperative branch of Kelun Pharmaceutical Factory (四川科倫大藥廠).

Mr. Liu has confirmed that (i) company secretarial matters such as conducting annual inspection of the above mentioned companies were assigned to certain specified staff in the respective company; (ii) the staff who are responsible for handling administrative matter, and the annual inspection and filing of annual report was inadvertently overlooked and those staff have left employment; (iii) there was no dishonest or fraudulent act on his part in inspect of the license revocation and non-compliance of the above mentioned companies. Mr. Liu further confirmed that up to Latest Practicable Date, he has not received any (i) claims or legal proceedings made or commenced against him by any creditors of the above mentioned companies or any third parties; (ii) notice or sanction by any relevant government authorities against him imposing any penalty or order for rectification or alleging that he is personally liable for the above mentioned non-compliances; or (iii) notice of disqualification by relevant authorities requiring him to cease to act as director of any PRC companies.

As of the Latest Practicable Date and save as disclosed above, there is no additional information relating to the Directors or Supervisors that is required to be disclosed pursuant to Rule 13.51(2)(h) to (v) of the Listing Rules.

JOINT COMPANY SECRETARIES

Mr. ZHOU Zejian (周澤劍), was appointed as one of the joint company secretaries of our Company with effect from January 30, 2023. For details of his biography, see “– Senior Management.”

Ms. FUNG Wai Sum (馮慧森), was appointed as one of the joint company secretaries of our Company with effect from January 30, 2023. Ms. Fung is a Senior Manager of Corporate Services of Tricor Services Limited, a global professional services provider specializing in integrated business, corporate and investor services. Ms. Fung has over 15 years of experience in the corporate secretarial field. She has been providing professional corporate services to Hong Kong listed companies as well as multinational, private and offshore companies.

Ms. Fung is currently the company secretary/joint company secretary of a few listed companies on The Stock Exchange of Hong Kong Limited. Ms. Fung is a Chartered Secretary, a Chartered Governance Professional and an Associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom. Ms. Fung obtained her master’s degree in professional accounting and corporate governance from City University of Hong Kong in November 2008.

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BOARD COMMITTEE

Our Company has established three committees under the Board pursuant the corporate governance practice requirements under the Hong Kong Listing Rules, including the audit committee, remuneration committee and nomination committee.

Audit Committee

We have established an audit committee in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code set out in Appendix 14 to the Listing Rules. The primary duties of the audit committee are to review and supervise the financial reporting process and internal control system of the Group, review and approve connected transactions and to advise the Board. The audit committee comprises three independent non-executive Director, namely, Dr. LI Yuedong (李越冬), Dr. TU Wenwei (涂文偉) and Dr. JIN Jinping (金錦萍). Dr. LI Yuedong (李越冬), is the chairperson of the committee, is appropriately qualified as required under Rules 3.10(2) and 3.21 of the Listing Rules.

Remuneration Committee

We have established a remuneration committee in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code set out in Appendix 14 to the Listing Rules. The primary duties of the remuneration committee are to review and make recommendations to the Board regarding the terms of remuneration packages, bonuses and other compensation payable to our Directors and senior management. The remuneration committee comprises one non-executive Directors and two independent non-executive Director, namely, Dr. ZHENG Qiang (鄭強), Mr. LIU Sichuan (劉思川) and Dr. JIN Jinping (金錦萍). Dr. ZHENG Qiang (鄭強), is the chairperson of the committee.

Nomination Committee

We have established a nomination committee in compliance with the Code on Corporate Governance set out in Appendix 14 to the Listing Rules. The primary duties of the nomination committee are to make recommendations to our Board regarding the appointment of Directors and Board succession. The nomination committee comprises one non-executive Directors and two independent non-executive Directors, namely, Mr. LIU Gexin (劉革新), Dr. ZHENG Qiang (鄭強) and Dr. TU Wenwei (涂文偉). Mr. LIU Gexin (劉革新), is the chairperson of the committee.

CORPORATE GOVERNANCE CODE

We recognize the importance of incorporating elements of good corporate governance in our management structure and internal control procedures so as to achieve effective accountability. We have adopted the code provisions stated in the Corporate Governance Code. We are committed to the view that the Board should include a balanced composition of executive Directors, non-executive Directors and independent non-executive Directors so that there is a strong independent element on the Board that can effectively exercise independent judgment.

To accomplish the high standards of corporate governance, we will comply with the Corporate Governance Code set out in Appendix 14 to the Listing Rules and the associated Listing Rules after the [REDACTED].

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

MANAGEMENT PRESENCE

According to Rule 8.12 of the Listing Rules, we must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong. Since the principal business operations of our Group are conducted in Mainland China, members of our senior management are, and are expected to continue to be, based in Mainland China. Further, as our executive Directors have a vital role in our Group’s operations, it is crucial for them to remain in close proximity to our Group’s central management located in Mainland China. Our Company does not and, for the foreseeable future, will not have a sufficient management presence in Hong Kong. We have applied for, and the Stock Exchange has [granted], a waiver from compliance with Rule 8.12 of the Listing Rules. For further details, see “Waivers from Strict Compliance with the Listing Rules and Exemption from Strict Compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance – Management Presence in Hong Kong.”

BOARD DIVERSITY POLICY

Our Board has adopted a board diversity policy which sets out the approach to achieve diversity on our Board. Our Company recognizes and embraces the benefits of having a diverse Board and sees increasing diversity at the Board level as an essential element in supporting the attainment of our Company’s strategic objectives and sustainable development. Our Company seeks to achieve Board diversity through the consideration of a number of factors, including but not limited to talent, skills, gender, age, cultural and educational background, ethnicity, professional experience, independence, knowledge and length of service. We will select potential Board candidates based on merit and his/her potential contribution to our Board while taking into consideration our own business model and specific needs from time to time. All Board appointments will be based on meritocracy and candidates will be considered against objective criteria, having due regard to the benefits of diversity on our Board.

Our Board has a balanced mix of knowledge, skills and experience. They completed studies in various majors including but without limitation to pharmaceuticals, medical science, marketing management and international business, finance and legal studies. We have four independent non-executive Directors who have different industry backgrounds. Furthermore, our Directors are of a wide range of age, from 35 to 71 years old. Taking into account our business model and specific needs as well as the presence of two female Directors out of a total of 11 Board members, we consider that the composition of our Board satisfies our board diversity policy.

We recognize the particular importance of gender diversity on our Board. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. Our board diversity policy provides that our Board shall take opportunities when selecting and making recommendations on suitable candidates for Board appointments with the aim of increasing the proportion of female members over time after [REDACTED]. In particular, taking into account the business needs of our Group and changing circumstances that may

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affect our business plans, we will actively 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 periodically reviewed by our nomination committee in order to develop a pipeline of potential successors to our Board and promote gender diversity. Additionally, female representatives of our investors are also considered as potential candidates for Board appointments. We will also ensure that there is gender diversity when recruiting staff at the mid- to senior- levels so that we have a pipeline of female senior management and potential successors to our Board going forward. We plan to offer well-rounded trainings to female employees whom we consider have the requisite experience, skills and knowledge of our operation and business, on topics including but not limited to business operation, management, accounting and finance, and legal compliance. We are of the view that such strategies will provide our Board with ample opportunities to identify capable female employees to be nominated as Directors in the future, fulfilling our aim to develop a pipeline of female candidates to achieve greater gender diversity in our Board in the long run. We believe that such a merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole. It is our objective to maintain an appropriate balance of gender diversity with reference to the stakeholders’ expectations and international and local recommended best practices.

Our nomination committee is responsible for ensuring the diversity of our Board members. After [REDACTED], our nomination committee will review our board diversity policy and its implementation annually to monitor its continued effectiveness and we will disclose the implementation of our board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives, in our corporate governance report on an annual basis.

COMPLIANCE ADVISER

We have appointed First Shanghai Capital Limited as our compliance adviser (the “**Compliance Adviser**”) pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Adviser will advise our Company in certain circumstances including:

- (a) before the publication of any regulatory announcement, circular, or financial report;
- (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- (c) where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and

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- (d) where the Stock Exchange makes an inquiry to our Company regarding unusual movements in the [REDACTED] or [REDACTED] of its listed securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

The term of appointment of our Compliance Adviser shall commence on the [REDACTED] and is expected to end on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts and confidentiality agreements with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

No Conflict

During the term of the employment contract, unless expressly agreed by us, the employee shall not engage in any part-time job or activities that create a conflict of interest with us. If the employee breaches this provision, we may choose to terminate the employment contract and hold the employee accountable for all of the loss incurred by us as a result of the breach.

Non-competition

Within a period from the date of the employee's departure (the "**Non-compete Period**") and during the course of employment by our Group, he/she shall not, among others, directly or indirectly engage in any business that competes with us. In addition, the employee shall not have any business connection with any our customer during the Non-compete Period (the "**Non-compete Requirement**"). We will notify the employee in written if the Non-compete Requirement is applicable to him/her. If applicable, we will pay monthly compensation to the relevant employee during the Non-compete Period.

Confidentiality

The employee shall keep in confidence and shall not disclose our trade secrets, including but not limited to our technical information and operational information in confidence during the term of their employment and thereafter.

Service Invention

The intellectual property rights in any invention, work or non-patent technical result that is (i) resulted from performing employee duties or (ii) developed mainly using our material, technologies and information shall belong to us.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

REMUNERATION OF DIRECTORS, SUPERVISORS AND FIVE HIGHEST PAID INDIVIDUALS

The compensation and remuneration of the Directors, Supervisors and members of the senior management of the Company are determined by the Shareholders’ meetings and the Board of Directors as appropriate in the form of salaries and bonuses. The Company also reimburses them for expenses which are necessary and reasonably incurred in providing services to the Company or discharging their duties in relation to the operations of the Company. When reviewing and determining the specific remuneration packages for our Directors, Supervisors and members of the senior management of the Company, the Shareholders’ meetings and the Board of Directors take into account factors such as salaries paid by comparable companies, time commitment, level of responsibilities, employment elsewhere in our Group and desirability of performance-based remuneration. As required by the relevant PRC laws and regulations, the Company also participates in various defined contribution plans organized by relevant provincial and municipal government authorities and welfare schemes for employees of the Company, including medical insurance, injury insurance, unemployment insurance, pension insurance, maternity insurance and housing provident fund.

Our Company offers executive Directors and senior management members, who are our employees, compensation in the form of salaries, bonuses, social security plans, housing provident fund plans and other benefits. The independent non-executive Directors receive compensation based on their responsibilities.

For details on the service contracts and appointment letters signed between the Company and our Directors and Supervisors, please refer to “Appendix VII – Statutory and General Information – C. Further Information about Our Directors, Supervisors and Substantial Shareholders – 1. Directors, Supervisors and Chief Executive – (ii) Particulars of Service Agreements.”

For the years ended December 31, 2021 and 2022, the total amount paid by us for payments of emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) to Directors were approximately RMB13.1 million and RMB7.9 million, respectively. For remuneration details of all Directors during the Track Record Period, please refer to Note 8 to the Accountants’ Report as set out in Appendix I to this document.

For the years ended December 31, 2021 and 2022, the total amount paid by us for payments of emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) to Supervisors were RMB2.2 million and RMB4.7 million, respectively.

The remuneration of Directors and Supervisors has been determined with reference to the salaries of comparable companies and their experience, duties and performance.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

For the years ended December 31, 2021 and 2022, the five highest remunerated individuals of our Company included 2 Directors and 1 Director, respectively, their remunerations were included in the total amount paid by us for the emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) of the relevant Directors. For the years ended December 31, 2021 and 2022, the total amount of remuneration and benefits in kind (if applicable) paid by us to the five highest remunerated individuals were approximately RMB25.1 million and RMB34.3 million, respectively.

It is estimated that remuneration equivalent to approximately RMB16.3 million in aggregate will be paid to the Directors and Supervisors by our Company for the year ending December 31, 2023, based on the arrangements in force as of the date of the document.

During the Track Record Period, no remuneration was paid by us nor receivable by Directors, Supervisors or the five highest remunerated individuals as incentives for joining or as rewards upon joining our Company. During the Track Record Period, no remuneration was paid by us nor receivable by Directors, past Directors, Supervisors, past Supervisors or the five highest remunerated individuals as compensation for leaving positions relating to management affairs in any subsidiary of the Company.

During the Track Record Period, none of our Directors have waived any remuneration. Save as disclosed above, during the Track Record Period, no other amounts shall be paid or payable by us or any of our subsidiaries to the Directors or the five highest remunerated individuals.

Save as disclosed above and indirect shareholding interest our Directors and Supervisors held through our Employee Incentive Plan, no Director or Supervisor is entitled to receive other special benefits from the Company.

Our Board will review and determine the remuneration and compensation packages of our Directors and senior management officers with, following the [REDACTED], the benefit of recommendations from the remuneration committee. Our remuneration committee will take into account salaries paid by comparable companies, time commitment and responsibilities of our Directors and performance of our Group.

EMPLOYEE INCENTIVE SCHEME

Please see “Appendix VII – Statutory and General Information – D. Employee Incentive Scheme” for details.

COMPETITION

Each of our executive Directors and non-executive Directors confirms that as of the Latest Practicable Date, he did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business and requires disclosure under Rule 8.10 of the Listing Rules.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and conversion of our Domestic Shares and Unlisted Foreign Shares into H Shares (assuming that the [REDACTED] is not exercised), the following persons are expected to have or be deemed or taken to have an interest and/or a short position in the Shares or underlying shares of our Company, which would be required to be disclosed to us and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO or will, directly or indirectly, be interested in 10% or more of the nominal value of share capital carrying rights to vote in all circumstances at the general meetings of the Company or any other members of the Group:

LONG POSITIONS IN THE SHARES OF THE COMPANY

Name of substantial shareholder	Nature of interest	Description of Shares	Shares held as of the Latest Practicable Date		Shares held immediately following the completion of the [REDACTED] and Conversion of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised)	
			Number	Percentage in the total issued share capital ⁽⁶⁾	Number	Percentage in the total issued share capital
Mr. LIU Gexin ⁽¹⁾	Interest in a controlled corporation	Domestic Shares	145,555,685	75.27%	136,555,685	[REDACTED]%
		H Shares	-	-	9,000,000	[REDACTED]%
Kelun Pharmaceutical ⁽¹⁾	Beneficial owner	Domestic Shares	115,555,685	59.75%	115,555,685	[REDACTED]%
		H Shares	-	-	-	-
	Interest in a controlled corporation ⁽²⁾	Domestic Shares	30,000,000	15.51%	21,000,000	[REDACTED]%
MSD ⁽³⁾	Beneficial owner	H Shares	-	-	9,000,000	[REDACTED]%
		Unlisted Foreign Shares	13,443,693	6.95%	-	-
		H Shares	-	-	13,443,693	[REDACTED]%

Notes:

- (1) Mr. LIU Gexin, the actual controller of Kelun Pharmaceutical, was deemed to be interested in the Shares of which are exercisable by Kelun Pharmaceutical under the SFO. Please see “Relationship with Our Controlling Shareholders – Overview” for details.
- (2) As of the Latest Practicable Date, our Employee Incentive Platforms, namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide, in aggregate, held 30,000,000 Domestic Shares of our Company. Please see “Appendix VII – Statutory and General Information – D. Employee Incentive Scheme” for details. Kelun Jingchuan, a wholly-owned subsidiary of Kelun Pharmaceutical, is the general partner of each of our Employee Incentive Platforms. Therefore, Kelun Pharmaceutical was entitled to exercise the voting rights attaching to the Shares held by our Employee Incentive Platforms.
- (3) As of the Latest Practical Date, MSD held 13,443,693 Unlisted Foreign Shares of our Company. MSD is a wholly-owned subsidiary of Merck & Co., Inc., a company listed on the New York Stock Exchange (stock code: MRK). Therefore, Merck & Co., Inc. was deemed to be interested in the Shares held by MSD under the SFO.

SUBSTANTIAL SHAREHOLDERS

Save as otherwise disclosed herein, our Directors are not aware of any persons who will, immediately following the [REDACTED] (assuming the [REDACTED] is not exercised), have any interests and/or short positions in the Shares or underlying shares of our Company which would fall 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, will be, directly or indirectly, interested in 10% or more of the nominal value of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

We are not aware of any arrangement which may result in any change of control in our Company at any subsequent date.

SHARE CAPITAL

SHARE CAPITAL

Immediately before the [REDACTED]

As of the Latest Practicable Date, our registered share capital was RMB193,382,499 divided into 169,210,389 Domestic Shares and 24,172,110 Unlisted Foreign Shares with a nominal value of RMB1.00 each.

In the course of the [REDACTED], the Shareholders of the Company had applied to the CSRC and obtained approval from the CSRC to convert certain Domestic Shares and Unlisted Foreign Shares held by them into H Shares, details of which are set out below:

Name of Shareholders	Number and description of Shares held as of the Latest Practicable Date	Number of Shares applied for conversion into H Shares	Percentage of number of Shares applied for conversion into H Shares to number of Shares held as of the Latest Practicable Date
Kelun Pharmaceutical	115,555,685 Domestic Shares	–	–
Kelun Huicai	7,500,000 Domestic Shares	2,250,000	30%
Kelun Huide	7,500,000 Domestic Shares	2,250,000	30%
Kelun Huineng	7,500,000 Domestic Shares	2,250,000	30%
Kelun Huizhi	7,500,000 Domestic Shares	2,250,000	30%
Dr. WANG Jingyi	5,700,000 Domestic Shares	2,850,000	50%
MSD	13,443,693 Unlisted Foreign Shares	13,443,693	100%
Wealthy Linkage	7,267,828 Unlisted Foreign Shares	3,633,914	50%
Leyue Capital	2,016,553 Unlisted Foreign Shares	1,008,277	50%
FIIF	7,144,177 Domestic Shares	–	–
Ningbo Daoyi	4,200,000 Domestic Shares	4,200,000	100%
Kexin Lunda	2,321,012 Domestic Shares	1,160,506	50%
Cinda Capital	386,835 Domestic Shares	386,835	100%
LAV Kecheng	771,852 Unlisted Foreign Shares	–	–

SHARE CAPITAL

Name of Shareholders	Number and description of Shares held as of the Latest Practicable Date	Number of Shares applied for conversion into H Shares	Percentage of number of Shares applied for conversion into H Shares to number of Shares held as of the Latest Practicable Date
Suzhou Likang	385,926 Domestic Shares	–	–
Anling Weijian	967,088 Domestic Shares	–	–
BOSC Xingling	734,987 Domestic Shares	734,987	100%
Gygnus Real	672,184 Unlisted Foreign Shares	537,748	80%
Wutong Juke	616,035 Domestic Shares	205,345	33.33%
Chengdu Wenjiang Emerging Industry Venture	386,835 Domestic Shares	386,835	100%
ZHOU Youcai	386,835 Domestic Shares	386,835	100%
Gao Ling Liangheng	231,556 Domestic Shares	115,778	50%
Longyi Technology	193,418 Domestic Shares	193,418	100%

Upon the Completion of the [REDACTED]

Immediately following the completion of the [REDACTED] and conversion of certain Domestic Shares and Unlisted Foreign Shares into H Shares, assuming the [REDACTED] is not exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate % of our enlarged share capital
Domestic Shares	149,589,850	[REDACTED]%
Unlisted Foreign Shares	5,548,478	[REDACTED]%
H Shares to be converted from Domestic Shares	19,620,539	[REDACTED]%
H Shares to be converted from Unlisted Foreign Shares	18,623,632	[REDACTED]%
H Shares to be [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	[REDACTED]	100%

SHARE CAPITAL

Assuming the [REDACTED] is exercised in full, the share capital of our Company upon completion of the [REDACTED] will be as follows:

Description of Shares	Number of Shares	Approximate % of the enlarged share capital
Domestic Shares	149,589,850	[REDACTED]%
Unlisted Foreign Shares	5,548,478	[REDACTED]%
H Shares to be converted from Domestic Shares	19,620,539	[REDACTED]%
H Shares to be converted from Unlisted Foreign Shares	18,623,632	[REDACTED]%
H Shares to be [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	[REDACTED]	100%

SHARES OF OUR COMPANY

Upon completion of the [REDACTED], the H Shares in issue, the Domestic Shares and the Unlisted Foreign Shares are ordinary Shares in the share capital of our Company, and are considered as one class of Shares. However, the H Shares generally may not be subscribed for by, or traded between, legal or natural persons of the PRC, apart from certain qualified domestic institutional investors in the PRC, the qualified PRC investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, and other persons who are entitled to hold the H Shares pursuant to relevant PRC laws and regulations or upon approval by any competent authorities.

RANKING

Domestic Shares, Unlisted Foreign 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. In addition to cash, dividends may be distributed in the form of Shares.

CONVERSION OF OUR DOMESTIC SHARES AND UNLISTED FOREIGN SHARES INTO H SHARES

All our Domestic Shares and Unlisted Foreign Shares are not listed or traded on any stock exchange. According to the regulations issued by the securities regulatory authorities of the State Council and our Articles of Association, the Domestic Shares and Unlisted Foreign Shares may be converted into H Shares, and such converted Shares may be [REDACTED] and traded on an overseas stock exchange provided that the conversion, [REDACTED] and trading of such converted Shares have been approved by the securities regulatory authorities of the

SHARE CAPITAL

State Council. Additionally, such conversion, trading and [REDACTED] shall meet any requirement of internal approval process and in all respects comply with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange.

Upon completion of the [REDACTED] and pursuant to the approval of the CSRC dated March 30, 2023, 19,620,539 Domestic Shares and 18,623,632 Unlisted Foreign Shares will be converted to H Shares on a one-for-one basis and be [REDACTED] for [REDACTED] on the Stock Exchange as set out below. The term “unlisted shares” is used to describe whether certain shares are listed on a stock exchange and is not unique to PRC laws.

[REDACTED] Review and Approval by the CSRC

In accordance with the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境内未上市股份申请「全流通」业务指引》) announced by the CSRC, H-share listed companies which apply for the conversion of shares into H shares for listing and circulation on the Stock Exchange 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 overseas shares by a joint stock company”. An H-share listed company may apply for a “Full Circulation” separately or when applying for refinancing overseas. An unlisted domestic joint stock company may apply for “full circulation” when applying for an overseas initial public offering.

The Company applied for a “full circulation” when applying for an overseas [REDACTED] with the CSRC on February 15, 2023, and submitted the application reports, authorization documents of the shareholders of unlisted shares for which an H-share “full circulation” was applied, explanation about the compliance of share acquisition and other documents in accordance with the requirements of the CSRC.

The Company has received the reply from the CSRC dated March 30, 2023 in relation to the approval of the overseas [REDACTED] and “Full Circulation”, pursuant to which:

- (1) the Company was approved to issue no more than [REDACTED] H Shares with a nominal value of RMB1.00 each, which are all ordinary shares, and upon this [REDACTED] the Company may be [REDACTED] on the Main Board of the Stock Exchange;
- (2) a total of 38,244,171 unlisted shares (with a nominal value of RMB1.00 each) held by certain Shareholders of the Company (the “**Full Circulation Participating Shareholders**”) were approved to be converted into H Shares, and the relevant Shares may be [REDACTED] on the Stock Exchange upon completion of the conversion.

This reply shall remain effective within 12 months from the date of approval.

SHARE CAPITAL

[REDACTED] Approval by the Stock Exchange

We have applied to the Listing Committee of the Stock Exchange for the granting of [REDACTED] of, and permission to [REDACTED], our H Shares to be [REDACTED] pursuant to the [REDACTED] (including any H Shares which may be issued pursuant to the exercise of the [REDACTED]) and the H Shares to be converted from 19,620,539 Domestic Shares and 18,623,632 Unlisted Foreign Shares on the Stock Exchange.

We will perform the following procedures for the conversion of unlisted shares into H Shares after receiving the approval of the Stock Exchange: (1) giving instructions to our [REDACTED] regarding relevant share certificates of the converted H Shares; and (2) enabling the converted H Shares to be accepted as eligible securities by [REDACTED] for deposit, clearance and settlement in the [REDACTED]. The Participating Shareholders may only [REDACTED] the Shares upon completion of following domestic procedures. Any application for [REDACTED] of the converted Shares on the Stock Exchange after our [REDACTED] is subject to prior notification by way of announcement to inform the Shareholders and the public of any proposed conversion.

Domestic Procedures

The Full Circulation Participating Shareholders may only [REDACTED] the Shares upon completion of the below arrangement procedures for the registration, deposit and transaction settlement in relation to the conversion and [REDACTED]:

- (a) We will appoint China Securities Depository and Clearing Corporation Limited (“CSDC”) as the nominal holder to deposit the relevant securities at CSDC (Hong Kong), which will then deposit the securities at [REDACTED] in its own name. CSDC, as the nominal holder of the Full Circulation Participating Shareholders, shall handle all custody, maintenance of detailed records, cross-border settlement and corporate actions, etc. relating to the converted H Shares for the Full Circulation Participating Shareholders;
- (b) We will engage a domestic securities company (the “**Domestic Securities Company**”) to provide services such as sending orders for trading of the converted H Shares and receipt of transaction returns. 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;

SHARE CAPITAL

- (c) The Shenzhen Stock Exchange shall authorize Shenzhen Securities Communication Co., Ltd. to provide services relating to transmission of trading orders and transaction returns 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;
- (d) According to the Notice of 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 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
- (e) 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 Domestic Shares and Unlisted Foreign Shares shall be reduced by the number of the Domestic Shares and Unlisted Foreign Shares converted and the number of H Shares shall be increased by the number of converted H Shares.

Conversion of Our Domestic Shares and Unlisted Foreign Shares into H Shares after completion of the [REDACTED]

According to the regulations by the securities regulatory authorities of the State Council and our Articles of Association, the holders of these Domestic Shares and Unlisted Foreign Shares may, at their own option, authorize the Company to file to the CSRC for conversion of their respective Domestic Shares and Unlisted Foreign Shares to H Shares after completion of the [REDACTED], and such converted Shares may be [REDACTED] and traded on an overseas stock exchange provided that the conversion, [REDACTED] and [REDACTED] of such converted Shares have been filed to the securities regulatory authorities of the State Council. Additionally, such conversion, [REDACTED] and [REDACTED] shall meet any requirement of internal approval process and in all respects comply with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. Save as disclosed in this document and to the best knowledge of our Directors, we are not aware of the intention of such existing Shareholders to convert their Domestic Shares or Unlisted Foreign Shares after completion of the [REDACTED].

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If any of the Domestic Shares or Unlisted Foreign Shares are to be converted, [REDACTED] and [REDACTED] as H Shares on the Stock Exchange, such conversion, the filings to the relevant PRC regulatory authorities, including the CSRC, and the approval of the Stock Exchange are necessary. Based on the procedures for the conversion of Domestic Shares and Unlisted Foreign Shares into H Shares as set forth below, we will apply for the [REDACTED] of all or any portion of the Domestic Shares and Unlisted Foreign Shares on the Stock Exchange as H Shares in advance of any proposed conversion after the [REDACTED] to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of Shares for entry on the H Share register. As the [REDACTED] of additional Shares after the [REDACTED] on the Stock Exchange is ordinarily considered by the Stock Exchange to be a purely administrative matter, it does not require such prior application for [REDACTED] at the time of our [REDACTED] in Hong Kong. Any application for [REDACTED] of the converted Shares on the Stock Exchange after our [REDACTED] is subject to prior notification by way of announcement to inform our Shareholders and the public of any proposed conversion.

Registration on our H Share register will be conditional on: (a) our H Share Registrar lodging with the Stock Exchange a letter confirming the proper entry of the relevant H Shares on the H Share register and the due dispatch of H Share certificates, and (b) the admission of the H Shares to trade on the Stock Exchange in compliance with the Listing Rules, the General Rules of [REDACTED] and the [REDACTED] in force from time to time. Until the converted Shares are re-registered on our H Share register, such Shares would not be [REDACTED] as H Shares. The relevant procedural requirements for the conversion of Domestic Shares and Unlisted Foreign Shares into H Shares are as follows:

- The holder of Domestic Shares and Unlisted Foreign Shares shall file to the CSRC or the relevant securities regulatory authorities of the State Council for the conversion of all or part of its Domestic Shares and Unlisted Foreign Shares into H Shares.
- The holder of Domestic Shares and Unlisted Foreign Shares shall issue to us a removal request in respect of a specified number of Shares attaching the relevant documents of title.
- Subject to our Company being satisfied with the authenticity of the documents and with the approval of our Board, we would then issue a notice to our H Share Registrar with instructions that, with effect from a specified date, our H Share Registrar is to issue the relevant holders with H Share certificates for such specified number of Shares.

SHARE CAPITAL

- The relevant Domestic Shares and Unlisted Foreign Shares will be withdrawn from the register of our Domestic Shares and Unlisted Foreign Shares and re-registered on our H Share register maintained in Hong Kong on the condition that:
 - (a) our [REDACTED] lodges with the Stock Exchange a letter confirming the proper entry of the relevant Shares on the H Share register and the due dispatch of share certificates; and
 - (b) the admission of the H Shares (converted from the Domestic Shares and Unlisted Foreign Shares) to [REDACTED] in Hong Kong will comply with the Listing Rules and the general rules of [REDACTED] and [REDACTED] in force from time to time.
- Upon completion of the conversion, the shareholding of the relevant holder of Domestic Shares and Unlisted Foreign Shares on the register of our Domestic Shares and Unlisted Foreign Shares will be reduced by such number of Domestic Shares and Unlisted Foreign Shares converted and the number of H Shares in the H Share register will correspondingly increase by the same number of Shares.
- We will comply with the Listing Rules to inform Shareholders and the public by way of an announcement of such fact not less than three days prior to the proposed effective date.

RESTRICTION ON TRANSFER OF SHARES ISSUED PRIOR TO THE [REDACTED]

The PRC Company Law provides that in relation to the [REDACTED] of a company, the shares of the company which have been issued prior to the [REDACTED] shall not be transferred within one year from the date of the [REDACTED]. Accordingly, Shares issued by our Company prior to the [REDACTED] shall be subject to this statutory restriction and shall not be transferred for a period of one year from the [REDACTED].

The Company will work with the Domestic Securities Company to be engaged by the Company to restrict the trading of the H Shares converted from unlisted Shares technically within one year after the [REDACTED].

Our Directors, Supervisors and members of senior management 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 [REDACTED], 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 our Shares held by our Directors, Supervisors and members of senior management, a summary of which is set out in “Appendix V – Summary of Articles of Association.”

SHARE CAPITAL

REGISTRATION OF SHARES NOT LISTED ON THE 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, an overseas listed company is required to register its shares that are not listed on the overseas stock exchange with CSDC within 15 Business Days upon [REDACTED] and provide a written report to the CSRC regarding the centralized registration and deposit of its unlisted shares as well as the current [REDACTED] and [REDACTED] of shares.

SHAREHOLDERS’ GENERAL MEETINGS

For details of circumstances under which our general Shareholders’ meetings are required, see “Appendix V – Summary of Articles of Association” and “Appendix IV – Summary of Principal Laws and Regulations.”

GENERAL MANDATE TO ISSUE SHARES

Subject to the completion of the [REDACTED], our Board has been granted a general mandate to allot and issue H Shares at any time within a period up to the date of the conclusion of the next annual general meeting of the Shareholders or the date on which our Shareholders pass a special resolution to revoke or change such mandate, whichever is earlier, upon such terms and conditions and for such purposes and to such persons as our Board in their absolute discretion deem fit, and to make necessary amendments to the Articles of Association, provided that, the number of H Shares to be [REDACTED] shall not exceed 20% of the number of H Shares in issue as at the [REDACTED].

For further details on this general mandate, see “Appendix VII – Statutory and General Information – A. Further Information about our Group – 4. Shareholders’ Resolutions.”

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our historical financial information, together with the accompanying notes, included in the Accountants’ Report set out in Appendix I to this document. Our consolidated financial information has been prepared in accordance with IFRS, which may differ in material aspects from generally accepted accounting principles in other jurisdictions. You should read the entire Accountants’ Report and not rely solely on the information contained in this section.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on assumptions and analyses made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, our actual performance may differ materially from those anticipated in these forward-looking statements, as a result of various risks and uncertainties over which we do not have full control. For details, see “Forward-looking Statements” and “Risk Factors.”

OVERVIEW

We are an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in China and globally. We take a systematic, indication-oriented approach to target the world’s prevalent or hard-to-treat cancers, and other diseases and conditions affecting a large and underserved population. Over the years, we have developed integrated capabilities encompassing all key drug development functionalities, which empower us to rapidly and strategically advance a differentiated and clinically valuable pipeline of 33 assets, including 14 in clinical stage as of the Latest Practicable Date.

We currently have no products approved for commercial sales and was loss-making during the Track Record Period. For the years ended December 31, 2021 and 2022, we had net losses of RMB889.8 million and RMB616.1 million, respectively, which primarily resulted from research and development expenses and administrative expenses. Leveraging our R&D capabilities and technology platforms, we had entered into nine out-license agreements as of the Latest Practicable Date. For the years ended December 31, 2021 and 2022, we recognized revenue of RMB32.3 million and RMB803.9 million, respectively, among which, RMB4.5 million and RMB785.9 million during the same years were in relation to these license and collaboration agreements.

We expect to incur significant expenses for at least the next several years as we continue to advance our preclinical research and clinical development plans, and to prepare for the commercialization of our drug candidates. Subsequent to the [REDACTED], our financial performance may fluctuate from period to period due to, among other factors, the development status of our drug candidates, regulatory approval timeline, and commercialization of our drug candidates after approval.

FINANCIAL INFORMATION

BASIS OF PREPARATION

Our historical financial information has been prepared in accordance with all applicable International Financial Reporting Standards (“IFRSs”), which comprise all applicable individual International Financial Reporting Standards, International Accounting Standards and Interpretations issued by the International Accounting Standards Board (“IASB”). The IASB has issued certain new and revised IFRSs. For the purpose of preparing the historical financial information, we have consistently adopted all applicable new and revised IFRSs throughout the Track Record Period, except for any new standards or interpretations that were not yet effective for the accounting period beginning on January 1, 2022. The revised and new accounting standards and interpretations issued but not yet effective for the accounting period beginning on January 1, 2022 and not yet adopted by us are described in detail in note 31 to the Accountants’ Report set out in Appendix I to this document. The historical financial information has been prepared under the historical cost convention. Our historical financial information also complies with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

We believe that the most significant factors affecting our results of operations and financial condition include the following:

Our Ability to Successfully Develop and Commercialize Our Drug Candidates

Our product pipeline includes drug candidates at various stages of development. Our business and results of operations depend on our ability to successfully advance our drug development programs, demonstrate satisfactory safety and efficacy clinical trial results, and obtain the requisite regulatory approvals and launch our products in our target markets as planned. As of the Latest Practicable Date, we had developed a pipeline of 33 assets, including 14 in clinical stage and four in IND-enabling stage. Five of our 14 clinical-stage drug candidates were in pivotal trial- or NDA registration-stage in China. See “Business – Our Pipeline” for more details.

Based on the expected approval timeline of each late-stage project in our pipeline, we expect to receive conditional marketing approval from the NMPA for A167 (PD-L1 mAb), our first innovative drug in NDA registration stage, in the second half of 2023 or the first half of 2024. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 in the China market in the second half of 2024 or the first half of 2025. After our drug candidates are commercialized, our business and results of operations will depend on the market acceptance and sales of our commercialized drugs. See also “Risk Factors – Risks Relating to the Development of Our Drug Candidates – Our business and prospects depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected.”

FINANCIAL INFORMATION

Our Existing and Future Collaboration and Licensing Arrangements

Our results of operations have been, and may continue to be, affected by our license and collaboration agreements with business partners. To date, we have entered into nine out-license agreements. For details, see “Business – License and Collaboration Arrangements.” For the years ended December 31, 2021 and 2022, we recognized revenue from license and collaboration agreements of RMB4.5 million and RMB785.9 million, respectively. These arrangements enable us to maximize the global value of the relevant assets and provide us with the capital support to advance our other pipeline assets and pursue opportunities for long-term growth.

Meanwhile, we may be required to pay license fees (such as upfront payments and milestone payments) pursuant to certain co-development, in-license or similar arrangements, or if we enter into such arrangements in the future. See “Business – Our License and Collaboration Arrangements.”

Following on the success of our existing license and collaboration agreements, we are actively exploring new partnership opportunities globally. For details, see “Business – Our Development Strategies – Continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline.” The timing and amount of upfront payments, milestone payments, royalties and other considerations in relation to our existing and future license and collaboration arrangements will have an impact on our results of operations.

Our Cost Structure

Our cost structure during the Track Record Period primarily consisted of costs and expenses in relation to R&D activities, administrative activities, and costs relating to financing activities.

Our costs and expenses were the largest component of our cost structure during the Track Record Period. Our costs and expenses related to research and development activities were significant as we advanced multiple drug development programs in various stages of the development life cycle. For the years ended December 31, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million and RMB1,122.8 million, respectively. Our cost of sales was incurred primarily in relation to our license and collaboration agreements with MSD and other licensing partners, and R&D services we provided to Kelun Group during the Track Record Period. Our cost of sales increased from RMB20.5 million for the year ended December 31, 2021 to RMB276.8 million for the year ended December 31, 2022, primarily attributable to the two license and collaboration agreements we entered into with MSD to develop SKB264 and SKB315, respectively.

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Our research and development expenses primarily consisted of staff costs and trial and testing expenses, including third-party contracting costs with respect to the engagement of CROs, clinical trial sites, principal investigators and other service providers to support our R&D activities. Our staff costs remained relatively stable in 2021 and 2022. Our trial and testing expenses fluctuated based on the timing and progress of our clinical trials and preclinical studies. We expect to continue to incur significant research and development expenses as we move our pipeline assets towards the clinic.

We also recorded significant administrative expenses in our operations. For the years ended December 31, 2021 and 2022, our administrative expenses amounted to RMB96.2 million and RMB95.3 million, respectively, which primarily consisted of staff costs. Our administrative expenses decreased from 2021 to 2022 as we streamlined our workforce to increase operating efficiency. The decrease was partially offset by [REDACTED] incurred in 2022 relating to the engagement of agents, legal counsel and other professional service providers for the [REDACTED].

During the Track Record Period, our finance costs primarily consisted of interest expenses on interest-bearing borrowings from Kelun Pharmaceutical, and interest expenses relating to the Shares we issued to Series A Investors. For the years ended December 31, 2021 and 2022, our finance costs were RMB112.6 million and RMB148.8 million, respectively. A substantial portion of such costs are not expected to continue after [REDACTED], as (i) all of our borrowings from Kelun Pharmaceutical had been fully settled as of the Latest Practicable Date, of which RMB2.5 billion was settled by way of debt-to-equity swap and the remaining was settled by cash; and (ii) the Shares we issued to Series A Investors will be converted into ordinary Shares upon [REDACTED].

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 bring them to commercialization, we expect to incur additional costs in relation to manufacturing, sales and marketing, and regulatory affairs, among other activities. We may also incur increased legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with license and collaboration agreements, and proceeds from our Series A Financing. We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. As our business continues to expand, we may require further funding through equity offerings, debt financing, license and collaboration arrangements, and other sources. Changes in our ability to fund our operations may affect our cash flow and results of operations. See also “Risk Factors – Risks Relating to Our Financial Position and Need for Additional Capital – We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.”

FINANCIAL INFORMATION

SIGNIFICANT ACCOUNTING POLICIES AND CRITICAL JUDGMENTS AND ESTIMATES

The preparation of financial statements in conformity with IFRSs requires our management to make judgments, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. Such judgments, estimates and assumptions are continually evaluated and are based on historical experience and various other factors, including expectations of future events, that are believed to be reasonable under the circumstances, from which our actual results may differ.

Set out below are a summary of the significant accounting policies, judgements and estimates which we believe are most important for understanding our results of operations and financial condition. See note 2 and 3 to the Accountants’ Report set out in Appendix I to this document for a detailed description of our significant accounting policies, judgments and estimates.

Significant Accounting Policies

Revenue and Other Income

Income is classified by us as revenue when it arises from the sale of goods or the provision of services. Revenue is recognized when control over a product or service is transferred to the customer, at the amount of promised consideration to which our Group is expected to be entitled, excluding those amounts collected on behalf of third parties. Revenue excludes value added tax or other sales taxes.

Further details of our revenue and other income recognition policies are as follows:

Revenue from Contracts with Customers

Revenue from License and Collaboration Agreements

We grant licenses of our intellectual property (the “License”) to our customers. The consideration for the License comprises a fixed element (the upfront payment) and variable elements (including but not limited to development milestones and sales-based royalties). The upfront fees are recognized as revenue when customers obtain rights to access the technology. Development milestone payments are included in the transaction price and recognized as revenue throughout the license period when it is highly probable that there will not be a subsequent reversal of a significant amount of revenue. Sales-based royalties are not included in the transaction price until customers make the sales.

Revenue from Provision of Research and Development Service

Research and development services are comprised of performance obligations which are capable of being distinct. Accordingly, the transaction price is allocated based on the relative stand-alone selling prices of the services.

FINANCIAL INFORMATION

For the research and development services that (i) the customer simultaneously receives and consumes the benefits provided by our performance as we perform; (ii) our performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or (iii) our performance does not create an asset with an alternative use to us and we have an enforceable right to payment for performance completed to date, we concluded that such services can be identified as a performance obligation satisfied over time. We use input methods to recognize revenue on the basis of our inputs to the satisfaction of a performance obligation relative to the total expected inputs to the satisfaction of that performance obligation.

Otherwise, revenue is recognized at a point in time when the customers accept and can benefit from such service.

Interest Income

Interest income is recognized as it accrues under the effective interest method using the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the gross carrying amount of the financial asset.

Government Grants

Government grants are recognized in the statement of financial position initially when there is reasonable assurance that they will be received and that we will comply with the conditions attaching to them. Grants that compensate us for expenses incurred are recognized as income in profit or loss on a systematic basis in the same periods in which the expenses are incurred. Grants that compensate us for the cost of an asset are recognized as deferred income and subsequently recognized in profit or loss over the useful life of the assets.

Dividends

Dividend income from unlisted investments is recognized when the shareholder’s right to receive payment is established.

Research and Development Expenses

Research and development expenses comprise all expenses that are directly attributable to research and development activities or that can be allocated on a reasonable basis to such activities. Expenditure on research activities is recognized as an expense in the period in which it is incurred. Expenditure on development activities is capitalized if the process is technically and commercially feasible and we have sufficient resources and the intention to complete development.

Property, Plant and Equipment (“PPE”)

Property, plant and equipment are stated at cost less accumulated depreciation and impairment losses.

Gains or losses arising from the retirement or disposal of an item of property, plant and equipment are determined as the difference between the net disposal proceeds and the carrying amount of the item and are recognized in profit or loss on the date of retirement or disposal.

FINANCIAL INFORMATION

Depreciation is calculated to write off the cost or valuation of items of property, plant and equipment, less their estimated residual value, if any, using the straight-line method over their estimated useful lives as follows:

– Machinery and Equipment	10 years
– Furniture, fixtures and others	3 – 5 years
– Vehicles	5 – 8 years
– Leasehold improvements	3 years

Where parts of an item of property, plant and equipment have different useful lives, the cost of the item is allocated on a reasonable basis between the parts and each part is depreciated separately. Both the useful life of an asset and its residual value, if any, are reviewed annually.

Construction in progress is stated at cost less impairment losses. Cost comprises the purchase costs of the asset and the related construction and installation costs. Construction in progress is transferred to property, plant and equipment when the asset is substantially ready for its intended use and depreciation will be provided at the appropriate rates in accordance with the depreciation policies specified above. No depreciation is provided in respect of construction in progress.

Employee Benefits

Short-term Employee Benefits and Contributions to Defined Contribution Retirement Plans

Salaries, annual bonuses, paid annual leave, contributions to defined contribution retirement plans and the cost of non-monetary benefits are accrued in the year in which the associated services are rendered by employees. Where payment or settlement is deferred and the effect would be material, these amounts are stated at their present values.

Contribution to appropriate local defined contribution retirement schemes are recognized as an expense in profit or loss as incurred.

Share-based Payments

The fair value of share-based payment awards granted to employees is recognized as an employee cost with a corresponding increase in a capital reserve within equity. The fair value is measured at grant date with reference to the price per share in the latest equity financing transaction, taking into account the terms and conditions upon which the share-based payment awards were granted. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the shares, the total estimated fair value of share-based payment awards is spread over the vesting period, taking into account the probability that the shares will vest.

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During the vesting period, the number of shares that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognized in prior periods is charged/credited to the profit or loss for the period of the review with a corresponding adjustment to the capital reserve. On vesting date, the amount recognized as an expense is adjusted to reflect the actual number of shares that vest (with a corresponding adjustment to the capital reserve).

Termination Benefits

Termination benefits are recognized at the earlier of when we can no longer withdraw the offer of those benefits and when we recognize restructuring costs involving the payment of termination benefits.

Interest-bearing Borrowings

Interest-bearing borrowings are measured initially at fair value less transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortized cost using the effective interest method. Interest expense is recognized in accordance with our accounting policy for borrowing costs.

Shares Issued

Shares issued are classified as equity if they bear discretionary dividends, do not contain any obligations to deliver cash or other financial assets and do not require settlement in a variable number of our equity instruments. Discretionary dividends on such shares issued are recognized as distributions within equity.

A financial liability is recognized if we have the obligation to redeem any equity instruments issued on a specific date or at the option of the shareholders (including the options that are only exercisable in case of occurrence of certain contingent triggering events). The liability is recognized and measured at the present value of the exercise price.

Contract Assets and Contract Liabilities

A contract asset is recognized when we recognize revenue before being unconditionally entitled to the consideration under the payment terms set out in the contract. Contract assets are assessed for expected credit losses (“ECL”) in accordance with the policy set out in note 2(h)(i) to the Accountants’ Report set out in the Appendix I to this document and are reclassified to receivables when the right to the consideration has become unconditional.

A contract liability is recognized when the customer pays non-refundable consideration before we recognize the related revenue. A contract liability would also be recognized if we have an unconditional right to receive non-refundable consideration before we recognize the related revenue. In such cases, a corresponding receivable would also be recognized.

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For a single contract with the customer, either a net contract asset or a net contract liability is presented. For multiple contracts, contract assets and contract liabilities of unrelated contracts are not presented on a net basis.

When the contract includes a significant financing component, the contract balance includes interest accrued under the effective interest method.

Critical Judgments and Estimates

Research and Development Expenses

Research and development expenses incurred on our pipelines are capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and 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 will assess the progress of each of the research and development projects and determine the criteria met for capitalization. During the Track Record Period, our research and development expenditures incurred did not meet these capitalization principles for any products and were expensed as incurred.

Recognition of Deferred Tax Assets

Deferred tax assets in respect of tax losses carried forward and deductible temporary differences are recognized and measured based on the expected manner of realization or settlement of the carrying amount of the relevant assets and liabilities, using tax rates enacted or substantively enacted at the end of each Track Record Period. In determining the carrying amounts of deferred tax assets, expected taxable profits are estimated which involves a number of assumptions relating to our operating environment and require a significant level of judgement exercised by the directors. Any change in such assumptions and judgement would affect the carrying amounts of deferred tax assets to be recognized and hence the net profit in future years.

Depreciation

Property, plant and equipment are depreciated on a straight-line basis over the estimated useful lives of the assets, after taking into account the estimated residual values. We review the estimated useful lives of the assets regularly in order to determine the amount of depreciation expenses to be recorded during the Track Record Period. The useful lives are based on our historical experience with similar assets and taking into account anticipated technological changes. The depreciation expenses for future periods are adjusted if there are significant changes from previous estimates.

FINANCIAL INFORMATION

DESCRIPTION OF SELECTED COMPONENTS OF THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth a summary of our consolidated statements of profit or loss and other comprehensive income for the years indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period.

	For the year ended December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Revenue	32,322	803,933
Cost of sales	(20,525)	(276,828)
Gross profit	11,797	527,105
Other net income/(expense)	34,843	(4,368)
Administrative expenses	(96,174)	(95,303)
Research and development expenses	(727,670)	(845,984)
Loss from operations	(777,204)	(418,550)
Finance costs	(112,591)	(148,814)
Loss before taxation	(889,795)	(567,364)
Income tax	–	(48,735)
Loss for the year attributable to equity shareholders of the Company	(889,795)	(616,099)
Other comprehensive income for the year (after tax)		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences on translation of financial statements of an overseas subsidiary	(3,910)	13,988
Other comprehensive income for the year	(3,910)	13,988
Total comprehensive income for the year attributable to equity shareholders of the Company	(893,705)	(602,111)

FINANCIAL INFORMATION

Revenue

During the Track Record Period, our revenue consisted of (i) revenue from our license and collaboration agreements. See “Business – Our License and Collaboration Arrangements” for details; and (ii) revenue from the research and development services we provided to Kelun Group and other third parties. The following table sets forth the components of our revenue in absolute amounts and as percentages of the total revenue for the years indicated:

	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Revenue from license and collaboration agreements	4,463	13.8	785,902	97.8
Revenue from provision of research and development services	27,859	86.2	18,031	2.2
Total	32,322	100.0	803,933	100.0

The significant increase in our revenue from 2021 to 2022 was primarily due to the increase of revenue from the two license and collaboration agreements we entered into with MSD to develop SKB264 and SKB315.

Cost of Sales

During the Track Record Period, our cost of sales was primarily related to the R&D activities we conducted in accordance with our license and collaboration agreements, and the R&D services we provided to Kelun Group and other third parties. Our cost of sales primarily consisted of (i) employee salaries and benefits for R&D staff; (ii) trial and testing expenses, primarily in relation to the engagement of CROs, clinical trial sites, principal investigators and other service providers; (iii) costs of raw materials and other consumables; (iv) depreciation and amortization expenses in connection with the machinery and equipment used; (v) tax and surcharge; and (vi) others, including office expenses and other miscellaneous expenses. The following table sets forth a breakdown of our cost of sales in absolute amounts and as percentages of the total cost of sales for the years indicated.

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	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Staff costs	13,063	63.6	69,560	25.1
Trial and testing expenses	1,846	9.0	157,907	57.0
Raw materials	745	3.6	22,123	8.0
Depreciation and amortization	603	2.9	9,603	3.5
Tax and surcharge	2,647	12.9	1,962	0.7
Others	1,621	8.0	15,673	5.7
Total	20,525	100.0	276,828	100.0

Gross Profit and Gross Profit Margin

Gross profit represents revenue less cost of sales. Gross profit margin represents gross profit as a percentage of revenue. For the years ended December 31, 2021 and 2022, our gross profits were RMB11.8 million and RMB527.1 million, respectively. For the same years, our gross profit margins were 36.5% and 65.6%, respectively.

Other Net Income/(Expense)

During the Track Record Period, our other net income or expense primarily consisted of (i) net foreign exchange gains or losses, which primarily reflected the increased or decreased value of assets or liabilities denominated in foreign currencies we hold resulting from fluctuations in exchange rate; (ii) government grants, mainly representing government subsidies from state and local government authorities in relation to our R&D activities and construction of our R&D and manufacturing facilities, which were one-off in nature and may vary from period to period; (iii) net loss or gain on disposal of property, plant and equipment; (iv) interest income from bank deposits; (v) net realized and unrealized gain on financial assets measured at fair value through profit or loss (“FVPL”); and (vi) others. The following table sets forth a breakdown of our other net income/(expense) in absolute amounts and as percentages of the total other net income/(expense) for the years indicated.

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	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Interest income from				
bank deposits	806	2.3	1,417	(32.4)
Net foreign exchange				
gains/(losses)	16,877	48.4	(31,944)	731.3
Government grants	16,716	48.0	20,254	(463.7)
Net (loss)/gain on disposal of				
property, plant and				
equipment	(5)	(0.0)	5,418	(124.0)
Net realized and unrealized				
gain on financial assets				
measured at FVPL	359	1.0	513	(11.7)
Others	90	0.3	(26)	0.5
Total	34,843	100.0	(4,368)	100.0

Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) staff costs, representing employee salaries and benefits, including the grant of restricted share units, for our administrative personnel; (ii) consulting service fees paid to agents, independent financial advisor and other professional service providers in the ordinary course of our business; (iii) depreciation and amortization expenses mainly associated with our office and equipment for administrative purposes; (iv) office and travel expenses in relation to our general operations; (v) [REDACTED] incurred in connection with the [REDACTED]; (vi) maintenance and repair expenses for office and equipment; and (vii) other miscellaneous expenses. The following table sets forth a breakdown of our administrative expenses in absolute amounts and as percentages of the total administrative expenses for the years indicated.

	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Staff costs	74,258	77.2	62,436	65.5
Consulting service fees	1,497	1.6	6,139	6.4
Depreciation and				
amortization expenses	4,480	4.7	7,727	8.1
Office and travel expenses	5,812	6.0	3,617	3.8
[REDACTED]	–	–	9,288	9.7

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	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Maintenance and repair expenses	5,194	5.4	2,272	2.4
Others	4,933	5.1	3,824	4.1
Total	96,174	100.0	95,303	100.0

Research and Development Expenses

During the Track Record Period, our research and development expenses primarily consisted of (i) staff costs, representing employee salaries and benefits, including the grant of restricted share units, for our R&D personnel; (ii) trial and testing expenses, primarily in relation to the engagement of CROs, clinical trial sites, principal investigators and other service providers; (iii) raw materials costs in relation to research and development of our drug candidates; (iv) depreciation, amortization and short-term lease expenses, primarily associated with machinery and equipment used in our research and development activities; and (v) others, such as utilities, maintenance and repair costs, and expenses incurred for the application and maintenance of intellectual property rights in relation to our R&D activities. The following table sets forth a breakdown of our research and development expenses in absolute amounts and as percentages of the total research and development expenses for the years indicated.

	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Staff costs	262,133	36.0	267,288	31.6
Trial and testing expenses	289,599	39.8	401,614	47.5
Raw materials	83,877	11.5	80,857	9.6
Depreciation, amortization and short-term lease expenses	57,288	7.9	48,754	5.8
Others	34,773	4.8	47,471	5.5
Total	727,670	100.0	845,984	100.0

FINANCIAL INFORMATION

Finance Costs

During the Track Record Period, our finance costs primarily consisted of (i) interest expenses on our borrowings from Kelun Pharmaceutical. For details of these borrowings, see “– Material Related Party Transactions”; (ii) interest expenses on financial instruments issued to investors, representing the Shares issued to Series A Investors; (iii) interest expenses on lease liabilities; and (iv) interest expenses on bank loans. We capitalized the interest expenses incurred for the construction in progress. The following table sets forth a breakdown of our finance costs in absolute amounts and as percentages of the total finance costs for the years indicated.

	For the year ended December 31,			
	2021		2022	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Interest expenses on borrowings from Kelun Pharmaceutical	90,209	80.1	108,301	72.8
Interest expenses on financial instruments issued to investors	27,295	24.2	40,943	27.5
Interest expenses on lease liabilities	164	0.1	5,605	3.8
Interest expenses on bank loans	1,574	1.5	2,893	1.9
Less: interest expenses capitalized into construction in progress	(6,651)	(5.9)	(8,928)	(6.0)
Total	112,591	100.0	148,814	100.0

Income Tax

During the Track Record Period, our income tax consisted of current tax and withholding tax. For the years ended December 31, 2021 and 2022, we recorded income tax of nil and RMB48.7 million, respectively. Our Directors confirm that during the Track Record Period, we had made all the required tax filings with the relevant tax authorities in the PRC and we are not aware of any outstanding or potential disputes with such tax authorities.

PRC

Effective from January 1, 2008, the PRC statutory income tax rate is 25% under the EIT Law. Our subsidiaries in the PRC are subject to PRC income tax at 25% unless otherwise specified.

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According to the EIT Law and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. We obtained our certificate of High and New Technology Enterprise on December 3, 2020 and are entitled to preferential income tax of 15% from 2020 to 2022.

United States

Pursuant to U.S. income tax laws and regulations and the Agreement between the Government of the People’s Republic of China and the United States of America for Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《中華人民共和國政府和美利堅合眾國政府關於對所得避免雙重徵稅和防止偷漏稅的協定》), we are subject to a 10% U.S. federal withholding tax, applied to certain payments made to us pursuant to the respective license and collaboration agreements.

Loss for the Year

For the years ended December 31, 2021 and 2022, we had net losses of RMB889.8 million and RMB616.1 million, respectively.

RESULTS OF OPERATIONS

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Revenue

Our revenue increased significantly from RMB32.3 million for the year ended December 31, 2021 to RMB803.9 million for the year ended December 31, 2022, primarily due to the increase of revenue from the two license and collaboration agreements we entered into with MSD to develop SKB264 and SKB315.

Cost of Sales

Our cost of sales increased significantly from RMB20.5 million for the year ended December 31, 2021 to RMB276.8 million for the year ended December 31, 2022, primarily in relation to the R&D activities we conducted in 2022 in accordance with our license and collaboration agreements with MSD to develop SKB264 and SKB315.

Gross Profit and Gross Profit Margin

Our gross profit increased significantly from RMB11.8 million for the year ended December 31, 2021 to RMB527.1 million for the year ended December 31, 2022. Accordingly, our overall gross profit margin increased significantly from 36.5% for the year ended December 31, 2021 to 65.6% for the year ended December 31, 2022, primarily because of our license and collaboration agreements with MSD.

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Other Net Income/(Expense)

We recorded other net income of RMB34.8 million for the year ended December 31, 2021, as compared to other net expenses of RMB4.4 million for the year ended December 31, 2022, which was primarily because we recorded net foreign exchange losses of RMB31.9 million for the year ended December 31, 2022, as compared to net foreign exchange gains of RMB16.9 million for the year ended December 31, 2021, as a result of the fluctuation in exchange rate of Renminbi against U.S. dollars.

Administrative Expenses

Our administrative expenses decreased by 0.9% from RMB96.2 million for the year ended December 31, 2021 to RMB95.3 million for the year ended December 31, 2022, which was primarily due to a decrease of RMB11.8 million in staff costs as we streamlined our workforce to increase operating efficiency, partially offset by an increase of RMB9.3 million in [REDACTED] incurred in relation to the [REDACTED].

Research and Development Expenses

Our research and development expenses increased by 16.3% from RMB727.7 million for the year ended December 31, 2021 to RMB846.0 million for the year ended December 31, 2022, primarily due to an increase of RMB112.0 million in trial and testing expenses, which was in line with the progress of our R&D activities.

Finance Costs

Our finance costs increased by 32.2% from RMB112.6 million for the year ended December 31, 2021 to RMB148.8 million for the year ended December 31, 2022, which was primarily due to (i) an increase of RMB18.1 million in interest expenses on our borrowings from Kelun Pharmaceutical, mainly associated with an increase of borrowings from Kelun Pharmaceutical; and (ii) an increase of RMB13.6 million in interest expenses on financial instruments issued to investors, following our issuance of Shares to Series A Investors in 2021.

Income Tax

We recorded income tax of RMB48.7 million for the year ended December 31, 2022, as compared to nil for the year ended December 31, 2021, primarily attributable to the U.S. federal withholding tax applied to certain payments made to us in 2022 pursuant to our license and collaboration agreements with MSD. We did not incur such tax expenses in 2021.

Loss for the Year

As a result of the foregoing, our loss for the year decreased by 30.8% from RMB889.8 million for the year ended December 31, 2021 to RMB616.1 million for the year ended December 31, 2022.

FINANCIAL INFORMATION

DESCRIPTION OF SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Non-current assets		
Property, plant and equipment	432,179	530,349
Right-of-use assets	41,987	117,475
Intangible assets	486	3,179
Other non-current assets	39,965	9,826
Total non-current assets	514,617	660,829
Current assets		
Inventories and other contract costs	78,707	52,636
Trade and other receivables	78,525	98,659
Amounts due from related parties	22,688	61,800
Restricted deposits	36,628	26,261
Cash and cash equivalents	81,793	92,960
Total current assets	298,341	332,316
Current liabilities		
Trade and other payables	185,256	243,405
Amounts due to related parties	221,912	206,908
Financial instruments issued to investors	539,078	580,021
Contract liabilities	109,038	163,976
Bank loans and other borrowings	2,387,967	2,890,787
Lease liabilities	1,663	82,264
Total current liabilities	3,444,914	4,167,361
Net current liabilities	(3,146,573)	(3,835,045)

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	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Total assets less current liabilities	(2,631,956)	(3,174,216)
Non-current liabilities		
Lease liabilities	1,252	41,292
Deferred income	10,678	10,678
Total non-current liabilities	11,930	51,970
Net liabilities	(2,643,886)	(3,226,186)

Property, Plant and Equipment

During the Track Record Period, our property, plant and equipment primarily consisted of (i) construction in progress, (ii) machinery and equipment, (iii) furniture, fixtures, and others, and (iv) leasehold improvements. Our property, plant and equipment increased by 22.7% from RMB432.2 million as of December 31, 2021 to RMB530.3 million as of December 31, 2022, primarily due to (i) an increase of RMB66.2 million in construction in progress primarily in relation to the construction of our R&D and manufacturing facilities, and office space; (ii) an increase of RMB11.2 million in leasehold improvements for our existing manufacturing facilities; (iii) an increase of RMB10.7 million in furniture, fixtures and others; and (iv) an increase of RMB10.3 million in machinery and equipment as we purchased new equipment to support our R&D activities.

Right-of-use Assets

During the Track Record Period, our right-of-use assets were primarily related to the leases of land use rights, properties and machinery and equipment used in our operations. Our right-of-use assets increased significantly from RMB42.0 million as of December 31, 2021 to RMB117.5 million as of December 31, 2022, primarily due to an increase of RMB64.6 million in machinery and equipment and an increase of RMB12.9 million in properties, as we recorded right-of-use assets on our balance sheet subsequent to January 1, 2022 in connection with the new three-year lease agreements with Kelun Pharmaceutical, which became effective on January 1, 2022.

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Other Non-current Assets

During the Track Record Period, our other non-current assets mainly represented prepayments we paid to suppliers for the construction of R&D and manufacturing facilities and purchase of equipment. Our other non-current assets decreased by 75.4% from RMB40.0 million as of December 31, 2021 to RMB9.8 million as of December 31, 2022, in line with the progress of our construction projects.

Inventories and Other Contract Costs

During the Track Record Period, our inventories and other contract costs consisted of (i) raw materials and low-value consumables purchased for our R&D activities and day-to-day operations; and (ii) other contract costs, primarily representing costs incurred for certain R&D activities we conducted in support of SKB264’s clinical development plan in accordance with the relevant license and collaboration agreement with MSD, for which we had not yet completed the relevant performance obligation to recognize revenue. The following table sets forth the details of our inventories and other contract costs as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB’000)</i>	<i>(RMB’000)</i>
Inventories		
Raw materials	45,590	48,643
Low-value consumables	5,134	3,993
Contract costs	27,983	–
Total	78,707	52,636

Our inventories and other contract costs decreased by 33.1% from RMB78.7 million as of December 31, 2021 to RMB52.6 million as of December 31, 2022, primarily due to a decrease of RMB28.0 million in other contract costs, mainly because we fulfilled the performance obligations and recognized revenue under the relevant license and collaboration agreement with MSD.

The following table sets forth an aging analysis of our inventories and other contract costs as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB’000)</i>	<i>(RMB’000)</i>
Within 1 year	67,978	37,625
1 to 2 years	5,676	10,210
2 to 3 years	5,053	2,268
Over 3 years	–	2,533
Total	78,707	52,636

As of April 30, 2023, RMB22.9 million, or 43.6%, of our inventories as of December 31, 2022, had been consumed.

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Our inventories with an age over three years increased by RMB2.5 million from December 2021 to December 2022, primarily because we procured a higher amount of durable low-value consumables in 2019. We do not foresee any significant recoverability issue with our inventories, and do not believe provision for impairment is necessary, considering that (i) our inventories are consisted exclusively of raw materials and low-value consumables for our R&D activities and day-to-day operations, a higher utilization of which is foreseeable in light of the rapid advancement of our pipeline and the fulfillment of license and collaboration agreements we have entered into; (ii) our inventories aged within one year accounted for 71.5% of the total inventories and other contract costs as of December 31, 2022; and (iii) we have taken stringent internal measures to enhance the inventory management. For example, we have appointed dedicated personnel who monitor aging conditions and utilization of our inventories to identify obsolete and slow-moving raw materials, if any, so that we can promptly take appropriate measures and adjust our procurement plan accordingly.

Trade and Other Receivables

During the Track Record Period, our trade and other receivables primarily consisted of (i) trade receivables mainly in relation to our provision of research and development services to third parties; (ii) other receivables, mainly representing social insurance contributions we made on behalf of our employees; (iii) value-added tax (“VAT”) recoverable in connection with the procurement of raw materials, third-party services, and machinery and equipment; and (iv) prepayments we made to CROs and other third-party service providers and suppliers of raw materials relating to our various preclinical studies and clinical trials. The following table sets forth the details of our trade and other receivables as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Trade receivables	146	–
Other receivables	2,165	1,846
Value-added tax (“VAT”) recoverable	45,557	40,785
Prepayments	30,657	56,028
	78,525	98,659
Total	78,525	98,659

Our trade and other receivables increased by 25.6% from RMB78.5 million as of December 31, 2021 to RMB98.7 million as of December 31, 2022, primarily due to an increase of RMB25.4 million in prepayments in line with the progress of our R&D activities.

As of April 30, 2023, RMB1,791 thousand, or 97.0%, of our other receivables as of December 31, 2022 had been subsequently settled.

The following table sets forth an aging analysis of our trade receivables presented based on the invoice date and net of loss allowance as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Within 3 months (inclusive)	146	–
Total	146	–
	146	–

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Amounts Due From Related Parties

During the Track Record Period, our amounts due from related parties primarily represented amounts due from Kelun Group in relation to our provision of R&D services and transfer of R&D projects to Kelun Group. Our amounts due from related parties increased significantly from RMB22.7 million as of December 31, 2021 to RMB61.8 million (all of which was trade related) as of December 31, 2022, primarily in relation to the transfer of cell therapy programs to Kelun Group in 2022. For details, see “– Material Related Party Transactions.”

As of April 30, 2023, RMB47.6 million, or 77.0% of our amounts due from related parties as of December 31, 2022 had been subsequently settled.

Restricted Deposits

During the Track Record Period, our restricted deposits mainly represented bank deposits pledged as collateral for the issuance of bills payable. We had restricted deposits of RMB36.6 million and RMB26.3 million as of December 31, 2021 and 2022, respectively, due to the settlement of our bills payable in 2022.

Cash and Cash Equivalents

During the Track Record Period, our cash and cash equivalents consisted of cash at bank, net of restricted bank deposits. We had cash and cash equivalents of RMB81.8 million and RMB93.0 million as of December 31, 2021 and 2022, respectively. The increase in our cash and cash equivalents primarily reflected the receipt of payments pursuant to our license and collaboration agreements with MSD for SKB264 and SKB315 in 2022.

As part of our cash management policy, we believe that we can make better use of our cash by utilizing wealth management products to better utilize our idle cash without interfering with our business operations or capital expenditures. During the Track Record Period, we purchased wealth management products issued by various commercial banks in the PRC from time to time, with a floating return being paid together with the principal on the maturity date, which were recognized as financial assets measured at FVPL. As of December 31, 2022 and April 30, 2023, the balances of our financial assets measured at FVPL were zero and RMB400.0 million, respectively.

To monitor and control the investment risks associated with our financial assets at FVPL, we have adopted a comprehensive set of internal policies and guidelines to manage our investment in financial assets at FVPL. We make investment decisions based on our estimated capital requirements and our annual budget, taking into account the duration, expected returns and risks of the wealth management product. We generally limit our purchases to low-risk and short-term products which are redeemable on demand from reputable commercial banks. Our finance department is responsible for proposing, analyzing and evaluating potential investment in wealth management products and led by our chief financial officer, Mr. ZHOU Zejian, who has over 15 years of experience in the financial industry. Investment proposals are subject to review and approval by our general manager, and approval of the Board or general meetings of shareholders if the investment amounts exceed thresholds specified in our investment policy.

After [REDACTED], we may continue to purchase low-risk wealth management products with a short maturity period based on our operational needs, strictly in accordance with our internal policies and measures and the requirements under Chapter 14 of the Listing Rules.

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Trade and Other Payables

During the Track Record Period, our trade and other payables consisted of (i) trade payables in connection with our procurement of raw materials, consumables, and third-party services; (ii) other payables, mainly representing other payables in connection with our day-to-day operations; (iii) bills payable primarily due to suppliers for the construction of our R&D and manufacturing facilities; (iv) accrued payroll and benefits, mainly including salaries and other welfare payables to our employees; and (v) other taxes payable. The following table sets forth the details of our trade and other payables as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Trade payables	98,341	123,259
Other payables	6,029	3,059
Bills payable	33,641	27,777
Accrued payroll and benefits	44,723	86,608
Other taxes payable	2,522	2,702
Total	185,256	243,405

Our trade and other payables increased by 31.4% from RMB185.3 million as of December 31, 2021 to RMB243.4 million as of December 31, 2022, primarily due to (i) an increase of RMB41.9 million in accrued payroll and benefits primarily due to the increase in salaries and year-end bonuses payable by us to our employees at the end of 2022; and (ii) an increase of RMB24.9 million in trade payables associated with the increase of procurement of raw materials and third-party services for our R&D activities.

The following table sets forth an aging analysis of our trade payables and bills payable presented based on the invoice date as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Within 1 year	131,142	149,663
1 to 2 years	346	642
2 to 3 years	320	307
More than 3 years	174	424
Total	131,982	151,036

As of April 30, 2023, RMB61.4 million, or 49.8%, of our trade payables as of December 31, 2022 had been subsequently settled.

Amounts Due to Related Parties

During the Track Record Period, our amounts due to related parties primarily represented amounts due to Kelun Group. Our amounts due to related parties decreased by 6.8% from RMB221.9 million as of December 31, 2021 to RMB206.9 million (RMB176.4 million of which was trade related) as of December 31, 2022, primarily as we reduced the procurement of R&D services from Kelun Group. For further details, see “– Material Related Party Transactions.”

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Financial Instruments Issued to Investors

During the Track Record Period, our financial instruments issued to investors represented the Shares issued to Series A Investors. We recorded financial instruments issued to investors of RMB539.1 million and RMB580.0 million as of December 31, 2021 and 2022, respectively.

Shares issued to Series A Investors are redeemable upon the occurrence of certain events stipulated in the Series A Share Subscription Agreement, which give rise to financial liabilities that are measured at the transaction price at initial recognition, and subsequently at amortized cost at an effective interest rate of 8%. For a discussion of our issuance of financial instruments to investors, see “History and Corporate Structure” in this document. For further information regarding our financial instruments issued to investors, see note 22 to the Accountants’ Report set out in Appendix I to this document.

Contract Liabilities

During the Track Record Period, our contract liabilities primarily represented amounts we received from MSD before we had reached the relevant milestones as contemplated in the relevant license and collaboration agreements. We recorded contract liabilities of RMB109.0 million and RMB164.0 million as of December 31, 2021 and 2022, respectively. The increase of our contract liabilities at the end of 2022 compared to 2021 was primarily the result of the payments we received from MSD pursuant to the relevant license and collaboration agreements.

As of April 30, 2023, RMB160.5 million, or 97.9%, of our contract liabilities as of December 31, 2022 had been subsequently recognized as revenue.

Bank Loans and Other Borrowings

During the Track Record Period, we obtained certain bank loans from certain commercial banks in the PRC and other borrowings from Kelun Pharmaceutical for supplementing our working capital. The following table sets forth the details of our bank loans and other borrowings as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>(RMB’000)</i>	<i>(RMB’000)</i>
Current		
Guaranteed bank loans	30,000 ⁽¹⁾	100,000 ⁽²⁾
Other borrowings from Kelun Pharmaceutical	2,357,967	2,790,787
Total	2,387,967	2,890,787

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Notes:

- (1) A short-term bank loan with a principal amount of RMB30.0 million and an effective interest rate of 3.85% per annum. This bank loan was secured by the actual controller of our Company, Mr. Liu Gexin. We fully repaid this loan in February 2022.
- (2) A short-term bank loan with a principal amount of RMB100.0 million and an effective interest rate of 3.75% per annum. This bank loan was secured by our Controlling Shareholder Kelun Pharmaceutical. We fully repaid this loan in February 2023.

As of December 31, 2021 and 2022, the outstanding balances of our bank loans were RMB30.0 million and RMB100.0 million, respectively.

The outstanding balances of our borrowings from Kelun Pharmaceutical were RMB2,358.0 million and RMB2,790.8 million as of December 31, 2021 and 2022, respectively. For details, see “– Material Related Party Transactions” and note 29 to the Accountants’ Report in Appendix I to this document.

LIQUIDITY AND CAPITAL RESOURCES

Our primary uses of cash during the Track Record Period were to fund our research and development activities, the construction of our research and development and manufacturing facilities, and purchase of equipment, machinery and intangible assets. We recorded net cash used in operating activities of RMB485.9 million and RMB270.8 million for the years ended December 31, 2021 and 2022, respectively. During the Track Record Period, we financed our operations primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from our Series A Financing. As of April 30, 2023, the latest practicable date for determining our indebtedness, we had cash and cash equivalents of RMB1,342.2 million. As of April 30, 2023, our unutilized banking facilities amounted to RMB638.5 million.

Current Assets and Liabilities

	As of December 31,		As of
	2021	2022	April 30,
	(RMB’000)	(RMB’000)	2023
			(RMB’000)
			(Unaudited)
Current assets			
Inventories and other contract costs	78,707	52,636	79,224
Trade and other receivables	78,525	98,659	201,836
Amounts due from related parties	22,688	61,800	19,483
Financial assets measured at FVPL	–	–	400,000
Restricted deposits	36,628	26,261	40,373
Cash and cash equivalents	81,793	92,960	1,342,166
	298,341	332,316	2,083,082
Total current assets	298,341	332,316	2,083,082

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	As of December 31,		As of April 30,
	2021	2022	2023
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
			<i>(Unaudited)</i>
Current liabilities			
Trade and other payables	185,256	243,405	251,718
Amounts due to related parties	221,912	206,908	38,986
Financial instruments issued to investors	539,078	580,021	1,952,303
Contract liabilities	109,038	163,976	747,711
Bank loans and other borrowings	2,387,967	2,890,787	–
Lease liabilities	1,663	82,264	40,313
Total current liabilities	<u>3,444,914</u>	<u>4,167,361</u>	<u>3,031,031</u>
Net current liabilities	<u>(3,146,573)</u>	<u>(3,835,045)</u>	<u>(947,949)</u>

We recorded net current liabilities during the Track Record Period primarily because we invested significant capital into the research and development of our extensive drug pipeline, and building up our technology platforms, R&D and manufacturing facilities and other capabilities to complement and support our business. These cash-intensive investments were financed in part through borrowings from Kelun Pharmaceutical and our Series A Financing, which were recorded as current liabilities on our balance sheet, and contributed to our net current liability position historically.

Our net current liabilities increased from RMB3,146.6 million as of December 31, 2021 to RMB3,835.0 million as of December 31, 2022, primarily attributable to (i) an increase of RMB502.8 million in bank loans and other borrowings to supplement our working capital; (ii) an increase of RMB80.6 million in current lease liabilities in connection with the new three-year lease agreements with Kelun Pharmaceutical; (iii) an increase of RMB58.1 million in trade and other payables, primarily due to the increase in salaries and year-end bonuses payable by us to our employees at the end of 2022 and the procurement of raw materials and third-party services for our R&D activities; (iv) an increase of RMB54.9 million in contract liabilities, representing amounts we received from MSD before we had reached the relevant milestones in our provision of research and development services; and (v) an increase of RMB40.9 million in financial instruments issued to investors, partially offset by (i) an increase of RMB39.1 million in amounts due from related parties, primarily in relation to the transfer of cell therapy programs to Kelun Group in 2022; and (ii) an increase of RMB20.1 million in trade and other receivables, primarily due to the increase of prepayments in line with the progress of our R&D activities. We recorded a decrease of RMB26.1 million in inventories and other contract costs under the current assets as of December 31, 2022, compared to December 31, 2021, mainly due to the decrease in other contract costs, as we fulfilled the performance obligations and recognized revenue in relation to certain R&D services we provided.

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Our net current liabilities decreased from RMB3,835.0 million as of December 31, 2022 to RMB947.9 million as of April 30, 2023, primarily because our borrowings from Kelun Pharmaceutical were fully settled, of which RMB2.5 billion was settled by way of debt-to-equity swap and the remaining was settled by cash. For details, see “– Liquidity and Capital Resources – Working Capital Sufficiency.”

We expect our net current liabilities position to improve significantly upon [REDACTED], as we recorded RMB1,952.3 million in financial instruments issued to investors as of April 30, 2023, which were attributable to the shares with preferential rights we issued to the Pre-[REDACTED] Investors and contributed to our net current liability position historically. Such shares will be converted into ordinary Shares upon [REDACTED], after which they will no longer be recorded as current liabilities on our statement of financial position. See “– Liquidity and Capital Resources – Working Capital Sufficiency” for details on our working capital sufficiency for at least the next 12 months from the date of this document. Going forward, we will closely monitor our liquidity position and maintain an adequate level of cash and cash equivalents to finance our operations and mitigate the impact of cash flow fluctuations.

Working Capital Sufficiency

Although we recorded significant net current liabilities during the Track Record Period, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses (including any production costs), for at least the next 12 months from the date of this document, primarily for the reasons set out below:

- *Settlement of borrowings from Kelun Pharmaceutical.* We had borrowings from Kelun Pharmaceutical of RMB2,358.0 million and RMB2,790.8 million, respectively, as of December 31, 2021 and 2022. We used such borrowings to support our operations. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. Primarily as a result of this debt-to-equity swap, our net current liabilities decreased to RMB947.9 million as of April 30, 2023. For further details, see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing – Share Subscription by Kelun Pharmaceutical” and “– Material Related Party Transactions.”

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- *Cash generated from our operations.* We plan to fund our future operations primarily with existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. In particular, we have entered into nine out-license agreements. As of April 30, 2023, we had received over US\$343.4 million of upfront, milestone and other payments arising from such agreements. Subject to the achievement of specified milestones and other terms set forth in the respective agreements (including termination clauses), we are entitled to future payments and intend to utilize them to fund our operations. See also “Business – Our License and Collaboration Arrangements.” Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. We expect to receive conditional marketing approval from the NMPA for A167 (PD-L1 mAb), our first innovative drug in NDA registration stage, in the second half of 2023 or the first half of 2024.
- *Conversion of Shares with preferential rights upon [REDACTED].* As of April 30, 2023, we recorded RMB1,952.3 million in financial instruments issued to investors, which were attributable to the shares with preferential rights we issued to the Pre-[REDACTED] Investors and contributed to our net current liability position historically. Such shares will be converted into ordinary Shares upon [REDACTED], after which they will no longer be recorded as current liabilities on our statement of financial position.
- *Cash burn rate.* Our cash burn rate refers to the average monthly amount of net cash used in operating activities, payment for property, plant and equipment and payment for intangible assets. We estimate that we will receive [REDACTED] of approximately HK\$[2,709.0] million in the [REDACTED], and assuming an [REDACTED] of HK\$[85.0] per Share, being the [REDACTED] of the indicative [REDACTED] range stated in this document. Assuming an average cash burn rate going forward of 1.0 times the level in the years ended December 31, 2021 and 2022, we estimate that our cash and cash equivalents as of April 30, 2023 will be able to maintain our financial viability for over 36 months from April 30, 2023, without taking into account 5.0% of the estimated [REDACTED] from the [REDACTED] (namely, the portion allocated for our working capital and other general corporate purposes); or, we estimate we will be able to maintain our financial viability for over 39 months from April 30, 2023, if we take into account 5.0% of the estimated [REDACTED] from the [REDACTED] (namely, the portion allocated for our working capital and other general corporate purposes).

Our Directors confirm that there has not been any material default on our part in the payment of trade and non-trade payables and borrowings, or breaches of covenants during the Track Record Period and up to the date of this document.

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Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the years indicated:

	For the year ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Operating cash flows before movements		
in working capital	(765,025)	(305,362)
Changes in working capital	279,083	34,515
Tax paid	–	–
Net cash used in operating activities	(485,942)	(270,847)
Net cash used in investing activities	(94,384)	(32,150)
Net cash generated from financing activities	647,316	313,452
Net increase in cash and cash equivalents	66,990	10,455
Cash and cash equivalents at beginning of year	16,189	81,793
Effect of foreign exchange rate changes	(1,386)	712
Cash and cash equivalents at the end of year	81,793	92,960

Net Cash Used in Operating Activities

For the year ended December 31, 2022, we had net cash used in operating activities of RMB270.8 million, which was primarily attributable to our loss before taxation of RMB567.4 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included finance costs of RMB148.8 million, depreciation of right-of-use assets of RMB41.4 million, an increase of RMB50.6 million in trade and other payables, net foreign exchange losses of RMB31.9 million, a decrease of RMB26.1 million in inventories and other contract costs, depreciation of property, plant and equipment of RMB23.3 million, and equity-settled share-based payment expenses of RMB19.8 million, and (ii) negative adjustments, which primarily included an increase of RMB21.0 million in amounts due from related parties, an increase of RMB20.1 million in trade and other receivables, and a decrease of RMB17.6 million in amounts due to related parties.

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For the year ended December 31, 2021, our net cash used in operating activities was RMB485.9 million, which was primarily attributable to our loss before taxation of RMB889.8 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included an increase of RMB173.8 million in amounts due to related parties, finance costs of RMB112.6 million, an increase of RMB109.0 million in contract liabilities, and an increase of RMB90.7 million in trade and other payables, and (ii) negative adjustments, which primarily included an increase of RMB37.3 million in inventories and other contract costs, an increase of RMB36.6 million in restricted bank deposits, an increase of RMB20.8 million in amounts due from related parties, and net foreign exchange gains of RMB16.9 million.

The negative operating cash flows we experienced during the Track Record Period primarily resulted from our cash-intensive research and development activities, while our drug candidates had not yet been approved or commercialized. For the years ended December 31, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million and RMB1,122.8 million, respectively.

We expect to generate income from sales of our drug products upon their successful commercialization, which will improve our operating cash flows. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 in the China market in the second half of 2024 or the first half of 2025. Furthermore, we are entitled to future payments under the out-license agreements we have entered into, which we also intend to utilize to fund our operations. See also “Business – Our License and Collaboration Arrangements.” In addition, we will continue to implement comprehensive measures to effectively control our operating costs and better utilize our idle cash. For example, we have set up a comprehensive budget management system covering all types of costs and expenses incurred in our daily operations, and strictly manage our budgets at the project and business department levels.

Net Cash Used in Investing Activities

For the year ended December 31, 2022, we had net cash used in investing activities of RMB32.2 million, primarily attributable to (i) the payment for investment in financial assets measured at FVPL of RMB370.0 million, and (ii) the payment for the purchase of property, plant and equipment of RMB33.7 million, partially offset by the proceeds from redemption of financial assets measure at fair value through profit or loss of RMB370.5 million.

For the year ended December 31, 2021, our net cash used in investing activities was RMB94.4 million, primarily attributable to (i) the purchase of property, plant and equipment of RMB94.1 million; and (ii) the payment for investment in financial assets measured at FVPL of RMB140.0 million, partially offset by the proceeds from redemption of financial assets of RMB140.4 million.

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Net Cash Generated From Financing Activities

For the year ended December 31, 2022, we had net cash generated from financing activities of RMB313.5 million, primarily attributable to (i) proceeds from borrowings from Kelun Pharmaceutical of RMB248.0 million; and (ii) proceeds from new bank loans of RMB115.0 million, partially offset by the repayment of bank loans of RMB45.0 million in 2022.

For the year ended December 31, 2021, our net cash generated from financing activities was RMB647.3 million, primarily attributable to (i) the proceeds from issuance of shares with preferential rights of RMB511.8 million; and (ii) the proceeds from borrowings from Kelun Pharmaceutical of RMB195.5 million, partially offset by the repayment of bank loans of RMB60.0 million in 2021.

CASH OPERATING COSTS

The following table sets forth our cash operating costs for the years indicated:

	For the year ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Costs relating to research and development of our Core Products		
Staff cost	51,085	109,369
Trial and testing expenses	61,769	89,665
Raw materials and others	15,046	57,256
<i>Subtotal</i>	127,900	256,290
Costs relating to research and development of our other drug candidates		
Staff cost	183,071	184,013
Trial and testing expenses	143,068	289,284
Raw materials and others	53,211	58,135
<i>Subtotal</i>	379,350	531,432
Total	507,250	787,722
Workforce employment costs ⁽¹⁾	74,258	62,490
Direct production costs ⁽²⁾	–	–
Product marketing ⁽³⁾	–	–
Non-income taxes, royalties and other governmental charges	–	–
Contingency allowances	–	–

Notes:

- (1) Workforce employment costs represent total non-research and development personnel costs mainly including salaries and benefits.
- (2) We had not commenced commercial-scale product manufacturing as of the Latest Practicable Date.
- (3) We had not commenced product sales as of the Latest Practicable Date.

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INDEBTEDNESS

As of December 31, 2021 and 2022 and April 30, 2023, being the most recent practicable date for determining our indebtedness, except as disclosed in the table below, we did not have any material indebtedness.

	As of December 31,		As of
	2021	2022	April 30,
	<i>RMB'000</i>	<i>RMB'000</i>	2023
			<i>RMB'000</i>
			<i>(Unaudited)</i>
Current			
Bank loans and other borrowings	2,387,967	2,890,787	–
Lease liabilities	1,663	82,264	40,313
Financial instruments issued to investors	539,078	580,021	1,952,303
Subtotal	2,928,708	3,553,072	1,992,616
Non-current			
Lease liabilities	1,252	41,292	42,647
Total	2,929,960	3,594,364	2,035,263

Bank Loans and Other Borrowings

As of December 31, 2021 and 2022 and April 30, 2023, the outstanding balances of our bank loans were RMB30.0 million, RMB100.0 million and nil, respectively. For details, see “– Description of Selected Items From the Consolidated Statements of Financial Position – Bank Loans and Other Borrowings.” As of the Latest Practicable Date, the remaining balance of our bank loans had been repaid in full by cash.

As of December 31, 2021 and 2022 and April 30, 2023, the outstanding balances of our borrowings from Kelun Pharmaceutical were RMB2,358.0 million, RMB2,790.8 million and nil, respectively. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. For further details, see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing – Share Subscription by Kelun Pharmaceutical” and “– Material Related Party Transactions.”

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Financial Instruments Issued to Investors

As of December 31, 2021 and 2022 and April 30, 2023, we recorded RMB539.1 million, RMB580.0 million and RMB1,952.3 million financial instruments issued to investors, respectively. For details, see “– Description of Selected Items From the Consolidated Statements of Financial Position – Financial Instruments Issued to Investors.”

Lease Liabilities

During the Track Record Period, we leased properties, machinery and equipment for our manufacturing and research and development activities and our office premises, generally with lease terms from one to ten years. We negotiate lease terms, which include different payment terms and conditions, on an individual basis. We recognized lease liabilities in respect of all of our leases, except for short-term leases and leases of low-value assets. The following table sets forth the details of our lease liabilities as of the dates indicated.

	As of December 31,		As of April 30,
	2021	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>
Within 1 year	1,663	82,264	40,313
After 1 year but within 2 years	250	41,148	42,200
After 2 years but within 5 years	572	144	447
After 5 years	430	–	–
Total	2,915	123,556	82,960

CAPITAL EXPENDITURES

During the Track Record Period, we incurred capital expenditures primarily to purchase our property, plant and equipment, and to purchase intangible assets. We funded our capital expenditure requirements during the Track Record Period mainly from borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from our Series A Financing. The following table sets forth the details of our capital expenditure for the years indicated.

	For the year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Payment for the purchase of property, plant and equipment	94,083	33,659
Payment for intangible assets	660	5,333
Total	94,743	38,992

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We plan to finance our future capital expenditures primarily with our existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. See the section “Future Plans and [REDACTED]” in the document for more details. We may reallocate the fund to be utilized on capital expenditures based on our ongoing business needs.

CAPITAL COMMITMENTS

As of December 31, 2021 and 2022, we had capital commitments contracted for but not yet provided of RMB86.3 million and RMB70.2 million, primarily in connection with contracts entered into for the construction of our R&D and manufacturing facilities. The following table sets forth our contractual commitments as of the dates indicated.

	As of December 31,	
	2021	2022
	(RMB'000)	(RMB'000)
Contracted, but not provided for: Construction in progress	86,332	70,151

CONTINGENT LIABILITIES

As of December 31, 2021 and 2022, we did not have any contingent liabilities. Our Directors confirm that there has been no material change in our contingent liabilities since December 31, 2022 to the date of this document.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

We did not have during the years presented, and we do not currently have, any off-balance sheet arrangements such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

KEY FINANCIAL RATIOS

The following table set forth our key financial ratios as of the dates indicated:

	As of December 31,	
	2021	2022
Current ratio ⁽¹⁾ (%)	8.7	8.0
Quick ratio ⁽²⁾ (%)	7.2	6.7

Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

FINANCIAL INFORMATION

Our current ratio decreased from 8.7% as of December 31, 2021 to 8.0% as of December 31, 2022, and our quick ratio decreased from 7.2% as of December 31, 2021 to 6.7% as of December 31, 2022, primarily because the increase of our current liabilities, which was mainly attributable to the increase of our borrowings from Kelun Pharmaceutical, outpaced the increase of our current assets, which was primarily attributable to the increase of amounts due from Kelun Group.

Our current ratio and quick ratio were relatively low during the Track Record Period, mainly as a result of our borrowings from to Kelun Pharmaceutical in the amount of RMB2,358.0 million and RMB2,790.8 million, respectively, as of December 31, 2021 and 2022, which were recorded as part of bank loans and other borrowings under current liabilities. As of April 30, 2023, our current ratio and quick ratio has increased to 68.7% and 66.1%, respectively, primarily because our borrowings from Kelun Pharmaceutical were fully settled, of which RMB2.5 billion was settled by way of debt-to-equity swap and the remaining was settled by cash. For details, see “– Liquidity and Capital Resources – Working Capital Sufficiency.”

MATERIAL RELATED PARTY TRANSACTIONS

During the Track Record Period, we had the following transactions with the following related parties that had material transaction amounts or balances with us:

	For the year ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Transactions of a trade nature		
<i>Provision of goods, services and PPE</i>		
Provision of R&D services to Kelun Group	19,919	16,190
Sales of low-value consumables to Kelun Group	1,040	148
Disposal of PPE to Kelun Group	1,065	16,036
	22,024	32,374
<i>Procurement of goods, services and PPE</i>		
Procurement of R&D services from Kelun Group	74,147	15,666
Procurement of goods from:		
– Kelun Group	1,644	7,270
– Kelun Medicine & Trade Group	9,838	25,605

FINANCIAL INFORMATION

	For the year ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Purchase of PPE from:		
– Kelun Group	36,990	7,217
– Kelun Medicine & Trade Group	–	620
	<u>122,619</u>	<u>56,378</u>
<i>Transfer of R&D projects to Kelun Group</i>	<u>–</u>	<u>39,761</u>
<i>Leasing of properties and equipment</i>		
Short-term leases for properties and equipment from:		
– Kelun Group	<u>42,892</u>	<u>–</u>
<i>Receiving other miscellaneous services from:</i>		
– Kelun Group	5,732	13,093
– Kelun Medicine & Trade Group	–	143
	<u>5,732</u>	<u>13,236</u>
Transactions of a non-trade nature		
<i>Amounts borrowed from Kelun Group</i>	<u>341,619</u>	<u>299,420</u>
<i>Amounts repaid to Kelun Group</i>	<u>48,251</u>	<u>–</u>
<i>Interest expense on borrowings from Kelun Pharmaceutical</i>	<u>90,209</u>	<u>108,301</u>
<i>Interest expense on lease liabilities to Kelun Group</i>	<u>63</u>	<u>5,571</u>

FINANCIAL INFORMATION

Provision of Goods, Services and PPE

During the Track Record Period, we provided R&D services and sold certain low-value consumables and equipment to Kelun Group from time to time in our ordinary course of business. The amount we charged for such goods, services and PPE increased from RMB22.0 million for the year ended December 31, 2021 to RMB32.4 million for the year ended December 31, 2022, primarily because we transferred certain equipments to Kelun Group in connection with the transfer of R&D projects in 2022.

Procurement of Goods, Services and PPE

During the Track Record Period, we procured R&D services from Kelun Group, and certain raw materials, low-value consumables, machinery and equipment from our other related parties, including Kelun Group and Kelun Medicine & Trade Group, from time to time in our ordinary course of business. Costs from procurement of goods, services and PPE decreased from RMB122.6 million for the year ended December 31, 2021 to RMB56.4 million for the year ended December 31, 2022, primarily due to (i) a decrease of RMB58.5 million in costs from procurement of R&D services from Kelun Group, and (ii) a decrease of RMB29.8 million from purchase of machinery and equipment from Kelun Group as we reduced the procurement of machinery and equipment from Kelun Group in 2022, partially offset by an increase of RMB15.8 million in procurement of drugs used in our clinical trials and consumables from Kelun Medicine & Trade Group to support our increased R&D activities. See also “Connected Transactions – Partially Exempt Continuing Connected Transactions – Procurement of R&D-related Drugs and Consumables.”

Transfer of R&D Projects to Kelun Group

We transferred our cell therapy programs to Kelun Group in December 2022 to focus on the research and development of our pipeline assets. We recorded RMB39.8 million in transaction amount for the year ended December 31, 2022 in relation to such R&D projects.

Leasing of Properties and Equipment

During the Track Record Period, we entered into short-term leases with Kelun Pharmaceutical for certain properties and equipment used in our ordinary course of business. We recorded short-term lease expenses of RMB42.9 million for the year ended December 31, 2021, compared to nil for the year ended December 31, 2022, as our new lease agreements with Kelun Pharmaceutical, which had a term of three years, became effective on January 1, 2022. In accordance with IFRS 16 (Leases), we recorded right-of-use assets on our balance sheet subsequent to January 1, 2022 in connection with this new lease, and lease liabilities representing our obligation to make lease payments to Kelun Pharmaceutical in the future. See also “Connected Transactions – One-off Connected Transactions.”

FINANCIAL INFORMATION

Receiving Other Miscellaneous Services

During the Track Record Period, we procured other miscellaneous services from our other related parties, primarily administrative services such as catering, shuttle buses, office park management, office cleaning and dormitory services. Costs for other miscellaneous services increased from RMB5.7 million for the year ended December 31, 2021 to RMB13.2 million for the year ended December 31, 2022, primarily due to the expansion of service scope provided by Kelun Group. See also “Connected Transactions – Fully Exempt Continuing Connected Transactions – Shared Administrative Services Framework Agreement.”

Amounts Borrowed From Kelun Group

Amounts borrowed from Kelun Group decreased from RMB341.6 million for the year ended December 31, 2021 to RMB299.4 million for the year ended December 31, 2022, primarily to satisfy part of our working capital and operational needs.

Amounts Repaid to Kelun Group

Amounts repaid to Kelun Group decreased from RMB48.3 million for the year ended December 31, 2021 to nil for the year ended December 31, 2022 as we did not settle any amounts in 2022. We settled the outstanding balance in full in January and February of 2023. See “– Material Related Party Transaction – Amounts Due to Related Parties” below for details.

Interest Expense on Borrowings From Kelun Pharmaceutical

During the Track Record Period, interest expense of borrowings to related parties was in relation to our borrowings from Kelun Pharmaceutical to satisfy part of our working capital and operational needs. Interest expense of borrowings increased from RMB90.2 million for the year ended December 31, 2021 to RMB108.3 million for the year ended December 31, 2022, mainly associated with an increase of borrowings from Kelun Pharmaceutical. Interest expense on borrowings from Kelun Pharmaceutical is expected to decrease significantly in 2023 due to the full settlement of such borrowings in January and February 2023.

Interest Expense on Lease Liabilities to Kelun Group

During the Track Record Period, interest expense of lease liabilities to related parties was primarily in relation to the leases we entered into with Kelun Pharmaceutical. Interest expense of lease liabilities increased from RMB63.0 thousand for the year ended December 31, 2021 to RMB5.6 million for the year ended December 31, 2022, primarily due to an increase in lease liabilities following the effectiveness of our new three-year lease agreements with Kelun Pharmaceutical.

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The below table sets forth outstanding balances with related parties as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Amounts due from related parties		
<i>Trade related:</i>		
Kelun Group	22,583	61,635
Kelun Medicine & Trade Group	–	165
	<u>22,583</u>	<u>61,800</u>
 <i>Non-trade related:</i>		
Kelun Group	105	–
	<u>105</u>	<u>–</u>
 Amounts due to related parties		
<i>Trade related:</i>		
Kelun Group	193,020	176,308
Kelun Medicine & Trade Group	279	113
	<u>193,299</u>	<u>176,421</u>
 <i>Non-trade related:</i>		
Kelun Group	26,494	29,063
Sichuan Kelun Doosan Biotechnology Co., Ltd.	2,119	1,424
	<u>28,613</u>	<u>30,487</u>
 <i>Other borrowings:</i>		
Kelun Pharmaceutical	2,357,967	2,790,787
	<u>2,357,967</u>	<u>2,790,787</u>
 <i>Lease liabilities:</i>		
Kelun Group	1,340	122,854
	<u>1,340</u>	<u>122,854</u>

FINANCIAL INFORMATION

Amounts Due From Related Parties

Trade Related

Our trade-related amounts due from related parties, including Kelun Group and Kelun Medicine & Trade Group, increased from RMB22.6 million as of December 31, 2021 to RMB61.8 million as of December 31, 2022, primarily in relation to the transfer of cell therapy programs to Kelun Group in 2022.

Non-trade Related

As of December 31, 2021 and 2022, our amounts due from Kelun Group of a non-trade nature amounted to RMB0.1 million and nil, respectively.

Amounts Due to Related Parties

Trade-related

Our trade-related amounts due to related parties, including Kelun Group and Kelun Medicine & Trade Group, decreased from RMB193.3 million as of December 31, 2021 to RMB176.4 million as of December 31, 2022, primarily as we reduced the procurement of R&D services from Kelun Group.

Non-trade Related

As of December 31, 2021 and 2022, we had amounts due to related parties of a non-trade nature of RMB28.6 million and RMB30.5 million, respectively. Our amounts due to related parties of a non-trade nature primarily represented Kelun Group’s investment in KLUS PHARMA after Kelun Development, a subsidiary of Kelun Pharmaceutical, transferred its shares in KLUS PHARMA to us in May 2020. For details, see “History – Our Subsidiaries – KLUS PHARMA.” As of April 30, 2023, we had settled such outstanding balance in full.

Borrowings From Kelun Pharmaceutical

As of December 31, 2021 and 2022, we had borrowings from Kelun Pharmaceutical of RMB2,358.0 million and RMB2,790.8 million, respectively, all of which were non-trade related, to satisfy part of our working capital and operational needs. Such borrowings had an effective interest rate of 4.35% per annum, which were unsecured and expected to be settled within three years. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. See “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing – Share Subscription by Kelun Pharmaceutical.”

FINANCIAL INFORMATION

Lease Liabilities

During the Track Record Period, we recorded trade-related lease liabilities in relation to the lease agreements we entered into with Kelun Pharmaceutical. Our lease liabilities due to Kelun Group increased significantly from RMB1.3 million as of December 31, 2021 to RMB122.9 million as of December 31, 2022, following the effectiveness of our new three-year lease agreements with Kelun Pharmaceutical.

It is the view of our Directors that each of the above transactions (i) was conducted in the ordinary and usual course of business and on normal commercial terms between the relevant parties, and (ii) does not distort our Track Record Period results or make our historical results not reflective of future performance. See note 29 to the Accountants’ Report as set out in Appendix I for a detailed information of transactions with related parties.

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to a variety of market risks and other financial risks, including credit risk, liquidity risk and currency risk as set out below. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance. For further details, including relevant sensitivity analysis, see note 27 in the Accountants’ Report set out in Appendix I of this document.

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to us. Our credit risk is primarily attributable to trade receivables. Our exposure to credit risk arising from cash and cash equivalents is limited because the counterparties are banks for which we consider to have low credit risk.

We also expect that there is no significant credit risk associated with other receivables and amounts due from related parties since the counterparties to these financial assets have no history of default.

We do not provide any guarantees which would expose us to credit risk.

Trade receivables

Our exposure to credit risk is influenced mainly by the individual characteristics of each customer. As of December 31, 2021, all of the total trade receivables were due from our five largest customers.

We trade mainly with recognized and creditworthy third parties. Individual credit evaluations are performed on all customers requiring credit over a certain amount. These take into account the customer’s past payment history, financial position and other factors. Trade receivables are due within 30 days from the date of billing. Normally, we do not obtain collateral from customers.

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We measure loss allowances for trade receivables at an amount equal to lifetime expected credit losses.

As our historical credit loss experience does not indicate significantly different loss patterns for different customer segments, the loss allowance based on past due status is not further distinguished between our different customer bases. As of December 31, 2021 and 2022, we did not provide any loss allowance for trade receivables. For further details, see note 27(a) of the Accountants' Report set out in Appendix I to this document.

Liquidity Risk

Our policy is to regularly monitor our liquidity requirements and our compliance with lending covenants, to ensure that we maintain sufficient reserves of cash to meet our liquidity requirements in the short and longer term. For further details and an analysis of the maturity profile of our financial liabilities at the end of each year during the Track Record Period, see note 27(b) of the Accountants' Report set out in Appendix I to the document.

Currency Risk

We are exposed to currency risk primarily through sales and purchases which give rise to cash and cash equivalents and amounts due to related parties that are denominated in a foreign currency, i.e., a currency other than the functional currency of the operations to which the transactions relate. The currencies giving rise to this risk is primarily U.S. dollars. Any significant exchange rate fluctuations of U.S. dollars against RMB may have a financial impact on us. We currently take certain foreign currency hedging measures and we did not experience any material impact on our operations resulting from fluctuation in exchange rates during the Track Record Period. However, our management monitors our foreign currency risk exposure and will review and adjust our hedging measures in accordance with our needs. For further details and an analysis of the sensitivity of our financial liabilities to foreign currency risk at the end of each year during the Track Record Period, see note 27(d) of the Accountants' Report set out in Appendix I to this document.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our earnings, capital requirements, overall financial condition and contractual restrictions. As confirmed by our PRC Legal Advisor, any future net profit that we make will have to be applied to make up for our historically accumulated losses in accordance with the PRC laws, after which we will be obliged to allocate 10% of our profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient profit to our statutory common reserve fund as described above. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future.

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DISTRIBUTABLE RESERVES

As of December 31, 2022, we did not have any reserves available for distribution to our Shareholders.

PROPERTIES AND VALUATION

In accordance with the requirement of Rule 5.07 of the Listing Rules, Cushman & Wakefield Limited, an independent property valuer, has valued our property interests as of March 31, 2023. Particulars of our property interests are set out in “Appendix VI – Property Valuation Report” to this document.

The table below sets out the reconciliation between the net book value of our property as of December 31, 2022 in the Accountants’ Report set out in Appendix I to this document and the market value of our property as of March 31, 2023, in the Property Valuation Report set out in Appendix VI to this document.

	(RMB in millions)
Net book value of our property as of December 31, 2022	335.1
Capital expenditures	6.5
Depreciation and adjustments	(0.2)
Net book value as of March 31, 2023	341.4
Valuation surplus as of March 31, 2023	50.3
Valuation as of March 31, 2023 as set out in Appendix VI to this document	391.7

[REDACTED]

[REDACTED] to be borne by us are estimated to be approximately HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), representing approximately 7.1% of the estimate [REDACTED] from the [REDACTED] assuming no Shares are issued pursuant to the [REDACTED]. The [REDACTED] consist of (i) [REDACTED] expenses, including [REDACTED], of approximately HK\$[REDACTED] million, and (ii) [REDACTED] expenses of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK\$[REDACTED] million, and (b) other fees and expenses of approximately HK\$[REDACTED] million. During the Track Record Period, the [REDACTED] charged to our consolidated statements of profit or loss were RMB[REDACTED] million (approximately HK\$[REDACTED] million) and the issue costs, which was recognized as prepayments and are expected to be deducted from equity upon the [REDACTED], were RMB[REDACTED] million (approximately HK\$[REDACTED] million). After the Track Record Period, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$153.8 million is expected to be accounted for as a deduction from equity upon the [REDACTED]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

FINANCIAL INFORMATION

UNAUDITED [REDACTED] ADJUSTED NET TANGIBLE ASSETS

The following unaudited [REDACTED] statement of our adjusted net tangible assets prepared in accordance with Rule 4.29 of the Listing Rules is to illustrate the effect of the [REDACTED] on our consolidated net tangible assets attributable to equity Shareholders of our Company as of December 31, 2022 as if the [REDACTED] had taken place on that date.

The unaudited [REDACTED] statement of our adjusted net tangible assets has been prepared for illustrative purposes only and, because of its hypothetical nature, it may not provide a true picture of our financial position had the [REDACTED] been completed as of December 31, 2022 or at any future date.

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, our Directors confirm that, except as disclosed in “Summary – Recent Developments and No Material Adverse Change” and up to the date of this document, there has been no material adverse change in our financial or trading position or prospects since December 31, 2022, which is the end date of the periods reported on in the Accountants’ Report included in Appendix I to this document, and there is no event since December 31, 2022 that would materially affect the information as set out in the Accountants’ Report included in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, they were not aware of any circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND [REDACTED]

FUTURE PLANS AND PROSPECTS

See “Business – Our Development Strategies” for a detailed description of our future plans.

[REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the indicative [REDACTED] range stated in this document. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the high end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED] million. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the low end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED] million.

Assuming an [REDACTED] at the [REDACTED] of the indicative [REDACTED] range and that the [REDACTED] is not exercised, we currently intend to apply these [REDACTED] for the following purposes:

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our Core Products, namely, SKB264 and A166;
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for SKB264, of which [REDACTED]% is expected to be used for clinical trial development and [REDACTED]% is expected to be used for commercialization.

The [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to advance the clinical trials of SKB264 in China, of which:

- (i) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund ongoing and planned clinical trials of SKB264 for TNBC. We commenced patient enrollment for SKB264’s pivotal phase 3 trial in August 2022 and anticipate to complete patient enrollment for this pivotal trial in the second half of 2023. We intend to use the results from this trial to support NDA submission to the NMPA by the end of 2023. We also initiated a phase 2 trial in July 2022 to evaluate SKB264 with or without A167 as a first-line treatment for advanced TNBC;
- (ii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund ongoing and planned clinical trials of SKB264 for NSCLC. We expect to commence a phase 3 trial in the second half of 2023 in EGFR-mutant NSCLC patients who have failed EGFR-TKI therapy. We

FUTURE PLANS AND [REDACTED]

intend to use the results from this trial to support NDA submission to the NMPA. We also initiated a phase 2 trial in May 2022 to evaluate SKB264 plus A167 with or without chemotherapy as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC; and

- (iii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund ongoing and planned clinical trials of SKB264 for HR+/HER2-BC. We expect to complete SKB264’s dose expansion study in HR+/HER2- BC patients as part of its global phase 1/2 trial and advance to phase 3 in the second half of 2023. We intend to use the results from this trial to support NDA submission to the NMPA.

For details of SKB264’s clinical development plan, see “Business – Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan”.

The [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to prepare for the anticipated commercial launch of SKB264. Subject to regulatory communications and marketing approval, we expect to launch SKB264 in the China market in the second half of 2024 or the first half of 2025. We plan to set up a fully-fledged commercialization team by the end of 2023 to oversee and coordinate the pre-marketing preparation for SKB264.

- approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for A166, of which [REDACTED]% is expected to be used for clinical trial development and [REDACTED]% is expected to be used for commercialization.

The [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to advance the clinical trials of A166 in China, of which:

- (i) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund ongoing and planned clinical trials of A166 for HER2+ BC. We plan to commence a confirmatory phase 3 trial of A166 as a 2L+ treatment for advanced HER2+ BC in the second half of 2023, pending consultation with the CDE; and
- (ii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund ongoing and planned clinical trials of A166 for HER2+ GC. We expect to conclude A166’s phase 1b trial in advanced HER2+ GC patients in the first half of 2024.

For details of A166’s clinical development plan, For details, see “Business – Our Pipeline – Oncology Franchise – ADCs – A166 – Clinical Development Plan”;

FUTURE PLANS AND [REDACTED]

The [REDACTED]%, or HK\$[REDACTED] million, is expected to be used for the preparation for the anticipated commercial launch of A166. Subject to regulatory communications and marketing approval, we expect to launch A166 in the China market in the second half of 2024 or the first half of 2025. We plan to set up a fully-fledged commercialization team by the end of 2023 to oversee and coordinate the pre-marketing preparation for A166.

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our other key products, including:
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the clinical development and preparation for NDA submission and anticipated commercialization of A140, including our ongoing pivotal phase 3 clinical trial for RAS wild-type mCRC, which we plan to complete primary analysis and file an NDA in the second half of 2023;
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the clinical development and anticipated commercialization of A167, including a phase 3 trial of A167 in combination with chemotherapy for RM-NPC with ongoing patient enrollment, as well as two ongoing phase 2 trials in combination with SKB264 for NSCLC and TNBC, respectively. See “Business – Our Pipeline – Oncology Franchise – Other Modalities – A167 – Clinical Development Plan”;
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the clinical development of A400, including its ongoing phase 1/2 clinical trial for advanced RET+ solid tumors and pivotal trial for 2L+ advanced RET+ NSCLC, as well as a planned pivotal trial for 1L advanced RET+ NSCLC that we anticipate to commence in the second half of 2023 and a pivotal trial anticipated to commence in the first half of 2024 for advanced RET+ MTC, and a planned phase 2 trial for adjuvant or neoadjuvant RET+ NSCLC. See “Business – Our Pipeline – Oncology Franchise – Other Modalities – A400 – Clinical Development Plan”;
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the clinical development of A223, including an ongoing phase 2 trial for severe AA and a planned pivotal phase 3 trial in the second half of 2023 for moderate-to-severe RA. See “Business – Our Pipeline – Non-oncology Franchise – A223 – Clinical Development Plan”;

FUTURE PLANS AND [REDACTED]

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the continued development of our technology platforms, advance our other existing pipeline assets, and explore and develop new drug candidates:
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to further develop our ADC, biologics and small molecule platforms. See “Business – Our Technology Platforms.”
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to expand our existing pipeline, of which approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the research and development of other existing non-key products, and approximately [REDACTED]%, or HK\$[REDACTED] million will be used to explore and develop new products.
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the expansion of our manufacturing capabilities and quality control system to support the anticipated commercialization of our late-stage assets. For instance, over the next few years, we plan to install one additional 2,000 L single-use bioreactor, bringing our total in-house capacity to 6,000 L. In addition, we plan to upgrade and improve our quality control system covering all major aspects of our operation, from R&D, procurement and supply chain to manufacturing. We will aim to adopt the latest and highest international standards used by pharmaceutical MNCs; and
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for working capital and other general corporate purposes.

The above [REDACTED] of the [REDACTED] from the [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the [REDACTED] of the indicative [REDACTED] range stated in this document.

If the [REDACTED] is exercised in full, the [REDACTED] that we will receive will be approximately HK\$[REDACTED] million, assuming an [REDACTED] of HK\$[REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED] range). In the event that the [REDACTED] is exercised in full, we intend to apply the additional [REDACTED] to the above purposes in the proportions stated above.

To the extent that the [REDACTED] from the [REDACTED] are not immediately used for the purposes described above and to the extent permitted by the relevant laws and regulations, they will be placed in short-term demand deposits with authorized and licensed commercial banks or financial institutions (as defined under the Securities and Futures Ordinance).

We will issue an appropriate announcement if there is any material change to the above proposed [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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STRUCTURE OF THE [REDACTED]

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[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

The following is the text of a report set out on pages I-1 to I-[68], received from the Company’s reporting accountants, KPMG, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.



ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF SICHUAN KELUN-BIOTECH BIOPHARMACEUTICAL CO., LTD., GOLDMAN SACHS (ASIA) L.L.C. AND CITIC SECURITIES (HONG KONG) LIMITED

Introduction

We report on the historical financial information of 四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-[4] to I-[68], which comprises the consolidated statements of financial position of the Group and the statements of financial position of the Company as at December 31, 2021 and 2022, the consolidated statements of profit or loss, 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 for each of the years ended December 31, 2021 and 2022 (the “Relevant Periods”), 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-[68] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [●] (the “Document”) in connection with the [REDACTED] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

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 and presentation set out in note 1 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.

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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’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in note 1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purpose of the accountants’ report, a true and fair view of the Company’s and the Group’s financial position as at December 31, 2021 and 2022 and of the Group’s financial performance and cash flows for the Relevant Periods in accordance with the basis of preparation and presentation set out in note 1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 26(b) to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

KPMG

Certified Public Accountants
8th Floor, Prince’s Building
10 Chater Road
Central, Hong Kong

[●]

APPENDIX I

ACCOUNTANTS’ REPORT

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 Relevant Periods, on which the Historical Financial Information is based, were audited by KPMG Huazhen LLP Chengdu Branch 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.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

(Expressed in Renminbi (“RMB”))

	Note	Year ended December 31,	
		2021 RMB’000	2022 RMB’000
Revenue	4	32,322	803,933
Cost of sales		<u>(20,525)</u>	<u>(276,828)</u>
Gross profit		11,797	527,105
Other net income/(expense)	5	34,843	(4,368)
Administrative expenses		(96,174)	(95,303)
Research and development expenses		<u>(727,670)</u>	<u>(845,984)</u>
Loss from operations		(777,204)	(418,550)
Finance costs	6(a)	<u>(112,591)</u>	<u>(148,814)</u>
Loss before taxation	6	(889,795)	(567,364)
Income tax	7(a)	<u>–</u>	<u>(48,735)</u>
Loss for the year attributable to equity shareholders of the Company		<u><u>(889,795)</u></u>	<u><u>(616,099)</u></u>
Loss per share	11		
Basic and diluted		<u><u>(8.90)</u></u>	<u><u>(5.74)</u></u>

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(Expressed in RMB)

		Year ended December 31,	
	<i>Note</i>	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Loss for the year		<u>(889,795)</u>	<u>(616,099)</u>
Other comprehensive income for the year (after tax)			
	<i>10</i>		
<i>Item that may be reclassified subsequently to profit or loss:</i>			
<i>Exchange differences on translation of financial statements of an overseas subsidiary</i>		<u>(3,910)</u>	<u>13,988</u>
Other comprehensive income for the year		<u>(3,910)</u>	<u>13,988</u>
Total comprehensive income for the year attributable to equity shareholders of the Company		<u>(893,705)</u>	<u>(602,111)</u>

The accompanying notes form part of the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(Expressed in RMB)

	<i>Note</i>	As at December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Non-current assets			
Property, plant and equipment	<i>12</i>	432,179	530,349
Right-of-use assets	<i>13</i>	41,987	117,475
Intangible assets		486	3,179
Other non-current assets	<i>14</i>	39,965	9,826
		<u>514,617</u>	<u>660,829</u>
Current assets			
Inventories and other contract costs	<i>15</i>	78,707	52,636
Trade and other receivables	<i>17</i>	78,525	98,659
Amounts due from related parties	<i>29(d)</i>	22,688	61,800
Restricted deposits	<i>18</i>	36,628	26,261
Cash and cash equivalents	<i>18</i>	81,793	92,960
		<u>298,341</u>	<u>332,316</u>
Current liabilities			
Trade and other payables	<i>19</i>	185,256	243,405
Amounts due to related parties	<i>29(d)</i>	221,912	206,908
Financial instruments issued to investors	<i>22</i>	539,078	580,021
Contract liabilities	<i>16</i>	109,038	163,976
Bank loans and other borrowings	<i>20</i>	2,387,967	2,890,787
Lease liabilities	<i>21</i>	1,663	82,264
		<u>3,444,914</u>	<u>4,167,361</u>
Net current liabilities		<u>(3,146,573)</u>	<u>(3,835,045)</u>
Total assets less current liabilities		<u>(2,631,956)</u>	<u>(3,174,216)</u>
Non-current liabilities			
Lease liabilities	<i>21</i>	1,252	41,292
Deferred income	<i>23</i>	10,678	10,678
		<u>11,930</u>	<u>51,970</u>
NET LIABILITES		<u>(2,643,886)</u>	<u>(3,226,186)</u>
CAPITAL AND RESERVES			
Share capital	<i>26(c)</i>	107,370	107,370
Reserves		<u>(2,751,256)</u>	<u>(3,333,556)</u>
TOTAL DEFICIT		<u>(2,643,886)</u>	<u>(3,226,186)</u>

The accompanying notes form part of the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

(Expressed in RMB)

	<i>Note</i>	As at December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Non-current assets			
Property, plant and equipment	<i>12</i>	362,015	458,026
Right-of-use assets	<i>13</i>	20,876	97,087
Intangible assets		486	3,179
Interests in subsidiaries	<i>33</i>	372,707	410,604
Other non-current assets	<i>14</i>	39,611	8,876
		<u>795,695</u>	<u>977,772</u>
Current assets			
Inventories and other contract costs	<i>15</i>	78,707	52,636
Trade and other receivables	<i>17</i>	74,095	93,660
Amounts due from related parties	<i>29(d)</i>	38,890	89,013
Restricted deposits	<i>18</i>	36,628	26,261
Cash and cash equivalents	<i>18</i>	79,924	90,362
		<u>308,244</u>	<u>351,932</u>
Current liabilities			
Trade and other payables	<i>19</i>	166,136	229,944
Amounts due to related parties	<i>29(d)</i>	378,254	377,723
Financial instruments issued to investors	<i>22</i>	539,078	580,021
Contract liabilities	<i>16</i>	109,038	163,976
Bank loans and other borrowings	<i>20</i>	2,319,252	2,819,449
Lease liabilities	<i>21</i>	739	82,072
		<u>3,512,497</u>	<u>4,253,185</u>
Net current liabilities		<u>(3,204,253)</u>	<u>(3,901,253)</u>
Total assets less current liabilities		<u>(2,408,558)</u>	<u>(2,923,481)</u>
Non-current liabilities			
Lease liabilities	<i>21</i>	1,252	40,942
Deferred income	<i>23</i>	7,678	7,678
		<u>8,930</u>	<u>48,620</u>
NET LIABILITIES		<u>(2,417,488)</u>	<u>(2,972,101)</u>
CAPITAL AND RESERVES			
Share capital	<i>26(c)</i>	107,370	107,370
Reserves		<u>(2,524,858)</u>	<u>(3,079,471)</u>
TOTAL DEFICIT		<u>(2,417,488)</u>	<u>(2,972,101)</u>

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Expressed in RMB)

	<i>Note</i>	Share capital RMB’000	Capital reserves RMB’000	Exchange reserves RMB’000	Accumulated losses RMB’000	Total RMB’000
Balance at January 1, 2021		76,689	130,223	(9,329)	(1,976,288)	(1,778,705)
Changes in equity for 2021						
Loss for the year		–	–	–	(889,795)	(889,795)
Exchange differences on translation of financial statements of an overseas subsidiary		–	–	(3,910)	–	(3,910)
Total comprehensive income		–	–	(3,910)	(889,795)	(893,705)
Issuance of new shares		18,830	3,198	–	–	22,028
Issuance of shares with preferential rights	22	11,851	499,932	–	–	511,783
Recognition of financial liabilities recognized for preferential rights issued to investors	22	–	(511,783)	–	–	(511,783)
Equity-settled share-based payment	24	–	6,496	–	–	6,496
Balance at December 31, 2021		<u>107,370</u>	<u>128,066</u>	<u>(13,239)</u>	<u>(2,866,083)</u>	<u>(2,643,886)</u>
Balance at January 1, 2022		<u>107,370</u>	<u>128,066</u>	<u>(13,239)</u>	<u>(2,866,083)</u>	<u>(2,643,886)</u>
Changes in equity for 2022						
Loss for the year		–	–	–	(616,099)	(616,099)
Exchange differences on translation of financial statements of an overseas subsidiary		–	–	13,988	–	13,988
Total comprehensive income		–	–	13,988	(616,099)	(602,111)
Equity-settled share-based payment	24	–	19,811	–	–	19,811
Balance at December 31, 2022		<u>107,370</u>	<u>147,877</u>	<u>749</u>	<u>(3,482,182)</u>	<u>(3,226,186)</u>

The accompanying notes form part of the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Expressed in RMB)

	<i>Note</i>	Year ended December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Operating activities			
Net cash used in operating activities	<i>18(b)</i>	<u>(485,942)</u>	<u>(270,847)</u>
Investing activities			
Payment for the purchase of property, plant and equipment		(94,083)	(33,659)
Proceeds from disposal of property, plant and equipment		–	6,329
Payment for intangible assets		(660)	(5,333)
Payment for investment in financial assets measured at fair value through profit or loss		(140,000)	(370,000)
Proceeds from redemption of financial assets measured at fair value through profit or loss		<u>140,359</u>	<u>370,513</u>
Net cash used in investing activities		<u>(94,384)</u>	<u>(32,150)</u>
Financing activities			
Proceeds from new bank loans	<i>18(c)</i>	30,000	115,000
Repayment of bank loans	<i>18(c)</i>	(60,000)	(45,000)
Proceeds from other borrowings from Kelun Pharmaceutical	<i>18(c)</i>	195,484	248,000
Repayment of other borrowings from Kelun Pharmaceutical	<i>18(c)</i>	(10,000)	–
Proceeds from issuance of new shares		22,028	–
Proceeds from issuance of shares with preferential rights	<i>22</i>	511,783	–
Interest paid	<i>18(c)</i>	(39,825)	(2,893)
Capital element of lease rentals paid	<i>18(c)</i>	(1,990)	(1,621)
Interest element of lease rentals paid	<i>18(c)</i>	<u>(164)</u>	<u>(34)</u>
Net cash generated from financing activities		<u>647,316</u>	<u>313,452</u>
Net increase in cash and cash equivalents		66,990	10,455
Cash and cash equivalents at January 1	<i>18(a)</i>	16,189	81,793
Effect of foreign exchange rate changes		<u>(1,386)</u>	<u>712</u>
Cash and cash equivalents at December 31	<i>18(a)</i>	<u>81,793</u>	<u>92,960</u>

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ACCOUNTANTS’ REPORT

NOTES TO THE HISTORICAL FINANCIAL INFORMATION

(Expressed in Renminbi unless otherwise stated)

1 BASIS OF PREPARATION AND PRESENTATION OF HISTORICAL FINANCIAL INFORMATION

(a) General Information

四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd., the “Company”) was incorporated in the People’s Republic of China (the “PRC”) on November 22, 2016 as a joint stock company with limited liability under the PRC Company Law.

The Company and its subsidiaries (together as “the Group”) were mainly engaged in researching and developing (“R&D”) service, manufacturing and commercialization of novel drugs.

The financial statements of the Company for the year ended 31 December 2021 were prepared in accordance with the Accounting Standards for Business Enterprises issued by the Ministry of Finance of the PRC and were audited by 四川博銳會計師事務所有限責任公司 (Sichuan Borui Certified Public Accountants Co., Ltd.).

No audited financial statements have been prepared for the Company for the year ended December 31, 2022.

(b) Subsidiaries

During the Relevant Periods and as at the date of this report, the Company has direct interests in its subsidiaries, all of which are private limited liability companies, the particulars of which are set out below:

Company name	Place and date of incorporation/ establishment	Particulars of issued and paid-in capital	Effective interest rate held by the Group		At the date of this report	Principal activities
			As at December 31			
			2021	2022		
Sichuan Konas Pharmaceutical Co., Ltd. 四川科納斯製藥有限公司 <i>(notes (i) and (ii))</i>	the PRC/ September 30, 2016	RMB4,000,000/ RMB nil	100%	100%	100%	Research and development
KLUS PHARMA INC. <i>(note (ii))</i>	the United States of America (the “USA”)/ October 31, 2014	USD100/ USD100	100%	100%	100%	Research and development
Sichuan Kelun-Biotech Biopharmaceutical Target Drugs Research Centre Co., Ltd. 四川科倫博泰生物靶向藥物工程研究中心有限公司 <i>(notes (i) and (ii))</i>	the PRC/ March 30, 2023	RMB100,000,000/ RMB nil	Not applicable	Not applicable	100%	Research and development

Notes:

- (i) The official name of the entity is in Chinese. The English translation of the name is for reference only. The entity is a limited liability company under the law of the PRC.
- (ii) No audited financial statements have been prepared.

All companies comprising the Group have adopted December 31 as their financial year end date.

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ACCOUNTANTS’ REPORT

(c) Basis of preparation

The Historical Financial Information has been prepared in accordance with all applicable International Financial Reporting Standards (“IFRSs”) which collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards (“IASs”) and Interpretations issued by the International Accounting Standards Board (“IASB”). Further details of the significant accounting policies adopted are set out in note 2.

The IASB has issued certain new and revised IFRSs. For the purpose of preparing this Historical Financial Information, the Group has consistently adopted all applicable new and revised IFRSs throughout the Relevant Periods except for any new standards or interpretations that are not yet effective for the accounting period beginning on January 1, 2022. The revised and new accounting standards and interpretations issued but not yet effective for the accounting period beginning on January 1, 2022 and not yet adopted by the Group are set out in note 31.

The Historical Financial Information also complies with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

As at December 31, 2022, the Group had net current liabilities of RMB3,835,045,000 and net liabilities of RMB3,226,186,000.

After taking into account of the Group’s cashflow projection for the next twelve months with reference to (i) On January 3, 2023, the Company, Sichuan Kelun Pharmaceutical Co., Ltd. (“Kelun Pharmaceutical”) and the other then Shareholders of the Company entered into a share subscription and debt-to-equity swap agreement, pursuant to which Kelun Pharmaceutical agreed to further subscribe for an aggregate of 51,255,685 Shares at the total subscription price of RMB2,650,000,000, among which RMB2,500,000,000 was settled through debt-to-equity swap and RMB150,000,000 was settled by cash on January 16, 2023; and (ii) the non-refundable upfront fee of USD175,000,000 (equivalent to RMB1,205,505,000) collected in March 2023 pursuant to an exclusive license and collaboration agreement which was entered into with a third party in December 2022, the directors of the Company consider that it is appropriate to prepare the Historical Financial Information on a going concern basis.

The accounting policies set out below have been applied consistently to all periods presented in the Historical Financial Information.

2 SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of measurement and presentation currency

The measurement basis used in the preparation of the Historical Financial Information is the historical cost basis except that financial assets measured at fair value through profit or loss (“FVPL”).

Item included in the financial statements of each entity in the Group are measured using the currency that best reflects the economic substance of the underlying events and circumstances relevant to the entity (the “Functional Currency”).

RMB and United States Dollar (“USD”) are the functional currencies for the Company and Company’s subsidiary established in the PRC and the USA respectively.

(b) Use of estimates and judgments

The preparation of the Historical Financial Information in conformity with IFRSs requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing 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.

Judgements made by management in the application of IFRSs that have significant effect on the Historical Financial Information and major sources of estimation uncertainty are discussed in note 3.

APPENDIX I

ACCOUNTANTS’ REPORT

(c) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. When assessing whether the Group has power, only substantive rights (held by the Group and other parties) are considered.

An investment in a subsidiary is consolidated into the consolidated financial statements from the date that control commences until the date that control ceases. Intra-group balances, transactions and cash flows and any unrealized profits arising from intra-group transactions are eliminated in full in preparing the consolidated financial statements. Unrealized losses resulting from intra-group transactions are eliminated in the same way as unrealized gains but only to the extent that there is no evidence of impairment.

Changes in the Group’s interests in a subsidiary that do not result in a loss of control are accounted for as equity transactions, whereby adjustments are made to the amounts of controlling interests within consolidated equity to reflect the change in relative interests, but no adjustments are made to goodwill and no gain or loss is recognized.

When the Group loses control of a subsidiary, it is accounted for as a disposal of the entire interest in that subsidiary, with a resulting gain or loss being recognized in profit or loss. Any interest retained in that former subsidiary at the date when control is lost is recognized at fair value and this amount is regarded as the fair value on initial recognition of a financial asset or, when appropriate, the cost on initial recognition of an investment in an associate or joint venture.

In the Company’s statement of financial position, an investment in a subsidiary is stated at cost less impairment losses (see note 2(h)), unless the investment is classified as held for sale (or included in a disposal group that is classified as held for sale).

(d) Other investments in debt and equity securities

The Group’s policies for investments in debt and equity securities, other than investments in subsidiaries, associates and joint ventures, are set out below.

Investments in debt and equity securities are recognized/derecognized on the date the Group commits to purchase/sell the investment. The investments are initially stated at fair value plus directly attributable transaction costs, except for those investments measured at fair value through profit or loss (FVPL) for which transaction costs are recognized directly in profit or loss. For an explanation of how the Group determines fair value of financial instruments, see note 27(e). These investments are subsequently accounted for as follows, depending on their classification.

(i) Investments other than equity investments

Non-equity investments held by the Group are classified into one of the following measurement categories:

- amortized cost, if the investment is held for the collection of contractual cash flows which represent solely payments of principal and interest. Interest income from the investment is calculated using the effective interest method (see note 2(r)(ii)).
- fair value through other comprehensive income (FVOCI) – recycling, if the contractual cash flows of the investment comprise solely payments of principal and interest and the investment is held within a business model whose objective is achieved by both the collection of contractual cash flows and sale. Changes in fair value are recognized in other comprehensive income, except for the recognition in profit or loss of expected credit losses, interest income (calculated using the effective interest method) and foreign exchange gains and losses. When the investment is derecognized, the amount accumulated in other comprehensive income is recycled from equity to profit or loss.
- fair value through profit or loss (FVPL) if the investment does not meet the criteria for being measured at amortized cost or FVOCI (recycling). Changes in the fair value of the investment (including interest) are recognized in profit or loss.

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(ii) *Equity investments*

An investment in equity securities is classified as FVPL unless the equity investment is not held for trading purposes and on initial recognition of the investment the Group makes an irrevocable election to designate the investment at FVOCI (non-recycling) such that subsequent changes in fair value are recognized in other comprehensive income.

Such elections are made on an instrument-by-instrument basis but may only be made if the investment meets the definition of equity from the issuer’s perspective. Where such an election is made, the amount accumulated in other comprehensive income remains in the fair value reserve (non-recycling) until the investment is disposed of. At the time of disposal, the amount accumulated in the fair value reserve (non-recycling) is transferred to retained earnings. It is not recycled through profit or loss. Dividends from an investment in equity securities, irrespective of whether classified as at FVPL or FVOCI, are recognized in profit or loss as other income in accordance with the policy set out in note 2(r)(iv).

(e) **Property, plant and equipment**

Property, plant and equipment are stated at cost less accumulated depreciation and impairment losses (see note 2(h)(ii)).

Gains or losses arising from the retirement or disposal of an item of property, plant and equipment are determined as the difference between the net disposal proceeds and the carrying amount of the item and are recognized in profit or loss on the date of retirement or disposal.

Depreciation is calculated to write off the cost of items of property, plant and equipment, less their estimated residual value, if any, using the straight-line method over their estimated useful lives as follows:

– Machinery and equipment	10 years
– Furniture, fixtures and others	3 – 5 years
– Vehicles	5 – 8 years
– Leasehold improvements	3 years

Where parts of an item of property, plant and equipment have different useful lives, the cost of the item is allocated on a reasonable basis between the parts and each part is depreciated separately. Both the useful life of an asset and its residual value, if any, are reviewed annually.

Construction in progress is stated at cost less impairment losses (see note 2(h)(ii)). Cost comprises the purchase costs of the asset and the related construction and installation costs.

Construction in progress is transferred to property, plant and equipment when the asset is substantially ready for its intended use and depreciation will be provided at the appropriate rates in accordance with the depreciation policies specified above.

No depreciation is provided in respect of construction in progress.

(f) **Intangible assets (other than goodwill)**

Intangible assets that are acquired by the Group are stated at cost less accumulated and impairment losses (see note 2(h)(ii)). Expenditure on internally generated goodwill and brands is recognized as an expense in the period in which it is incurred.

Amortization of intangible assets with finite useful lives is charged to profit or loss on a straight-line basis over the assets’ estimated useful lives. The following intangible assets with finite useful lives are amortized from the date they are available for use and their estimated useful lives are as follows:

– Software	2 years
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Both the period and method of amortization are reviewed annually.

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(g) Leased assets

At inception of a contract, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Control is conveyed where the customer has both the right to direct the use of the identified asset and to obtain substantially all of the economic benefits from that use.

As a lessee

Where the contract contains lease component(s) and non-lease component(s), the Group has elected not to separate non-lease components and accounts for each lease component and any associated non-lease components as a single lease component for all leases.

At the lease commencement date, the Group recognizes a right-of-use asset and a lease liability, except for short-term leases that have a lease term of 12 months or less and leases of low-value assets. When the Group enters into a lease in respect of a low-value asset, the Group decides whether to capitalize the lease on a lease-by-lease basis. The lease payments associated with those leases which are not capitalized are recognized as an expense on a systematic basis over the lease term.

Where the lease is capitalized, the lease liability is initially recognized at the present value of the lease payments payable over the lease term, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, using a relevant incremental borrowing rate. After initial recognition, the lease liability is measured at amortized cost and interest expense is calculated using the effective interest method. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability and hence are charged to profit or loss in the accounting period in which they are incurred.

The right-of-use asset recognized when a lease is capitalized is initially measured at cost, which comprises the initial amount of the lease liability plus any lease payments made at or before the commencement date, and any initial direct costs incurred. Where applicable, the cost of the right-of-use assets also includes an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, discounted to their present value, less any lease incentives received. The right-of-use asset is subsequently stated at cost less accumulated depreciation and impairment losses (see note 2(h)(ii)).

The lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, or there is a change in the Group’s estimate of the amount expected to be payable under a residual value guarantee, or there is a change arising from the reassessment of whether the Group will be reasonably certain to exercise a purchase, extension or termination option. When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The lease liability is also remeasured when there is a change in the scope of a lease or the consideration for a lease that is not originally provided for in the lease contract (“lease modification”) that is not accounted for as a separate lease. In this case the lease liability is remeasured based on the revised lease payments and lease term using a revised discount rate at the effective date of the modification.

In the consolidated statement of financial position, the current portion of long-term lease liabilities is determined as the present value of contractual payments that are due to be settled within twelve months after the reporting period.

(h) Credit losses and impairment of assets

(i) *Credit losses from financial instruments*

The Group recognizes a loss allowance for expected credit losses (ECLs) on the following items:

- financial assets measured at amortized cost (including cash and cash equivalents, trade receivables and other receivables);

Other financial assets measured at fair value, including equity securities measured at FVPL, are not subject to the ECL assessment.

Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all expected cash shortfalls (i.e. the difference between the cash flows due to the Group in accordance with the contract and the cash flows that the Group expects to receive).

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The expected cash shortfalls are discounted using the following discount rates where the effect of discounting is material:

- fixed-rate financial assets, trade and other receivables and contract assets: effective interest rate determined at initial recognition or an approximation thereof;
- variable-rate financial assets: current effective interest rate.

The maximum period considered when estimating ECLs is the maximum contractual period over which the Group is exposed to credit risk.

In measuring ECLs, the Group takes into account reasonable and supportable information that is available without undue cost or effort. This includes information about past events, current conditions and forecasts of future economic conditions.

ECLs are measured on either of the following bases:

- 12-month ECLs: these are losses that are expected to result from possible default events within the 12 months after the reporting date; and
- lifetime ECLs: these are losses that are expected to result from all possible default events over the expected lives of the items to which the ECL model applies.

Loss allowances for trade receivables and contract assets are always measured at an amount equal to lifetime ECLs. ECLs on these financial assets are estimated using a provision matrix based on the Group’s historical credit loss experience, adjusted for factors that are specific to the debtors and an assessment of both the current and forecast general economic conditions at the reporting date.

For all other financial instruments, the Group recognizes a loss allowance equal to 12-month ECLs unless there has been a significant increase in credit risk of the financial instrument since initial recognition, in which case the loss allowance is measured at an amount equal to lifetime ECLs.

Significant increases in credit risk

In assessing whether the credit risk of a financial instrument has increased significantly since initial recognition, the Group compares the risk of default occurring on the financial instrument assessed at the reporting date with that assessed at the date of initial recognition. In making this reassessment, the Group considers that a default event occurs when (i) the borrower is unlikely to pay its credit obligations to the Group in full, without recourse by the Group to actions such as realizing security (if any is held); or (ii) the financial asset is 30 days past due. 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 since initial recognition:

- failure to make payments of principal or interest on their contractually due dates;
- an actual or expected significant deterioration in a financial instrument’s external or internal credit rating (if available);
- an actual or expected significant deterioration in the operating results of the debtor; and
- existing or forecast changes in the technological, market, economic or legal environment that have a significant adverse effect on the debtor’s ability to meet its obligation to the Group.

Depending on the nature of the financial instruments, the assessment of a significant increase in credit risk is performed on either an individual basis or a collective basis. When the assessment is performed on a collective basis, the financial instruments are grouped based on shared credit risk characteristics, such as past due status and credit risk ratings.

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ECLs are remeasured at each reporting date to reflect changes in the financial instrument's credit risk since initial recognition. Any change in the ECL amount is recognized as an impairment gain or loss in profit or loss. The Group recognizes an impairment gain or loss for all financial instruments with a corresponding adjustment to their carrying amount through a loss allowance account.

Basis of calculation of interest income

Interest income recognized in accordance with note 2(r)(ii) 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 the amortized cost (i.e. the gross carrying amount less loss allowance) of the financial asset.

At each reporting date, the Group assesses whether a financial asset is credit-impaired. A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.

Evidence that a financial asset is credit-impaired includes the following observable events:

- significant financial difficulties of the debtor;
- a breach of contract, such as a default or past due event;
- it becoming probable that the borrower will enter into bankruptcy or other financial reorganization;
- significant changes in the technological, market, economic or legal environment that have an adverse effect on the debtor; or
- the disappearance of an active market for a security because of financial difficulties of the issuer.

Write-off policy

The gross carrying amount of a financial asset, lease receivable or contract asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery. This is generally the case when the Group determines that the debtor does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off.

Subsequent recoveries of an asset that was previously written off are recognized as a reversal of impairment in profit or loss in the period in which the recovery occurs.

(ii) Impairment of other non-current assets

Internal and external sources of information are reviewed at the end of each reporting period to identify indications that the following assets may be impaired or, except in the case of goodwill, an impairment loss previously recognized no longer exists or may have decreased:

- property, plant and equipment;
- right-of-use assets;
- intangible assets;
- other non-current assets; and
- investments in subsidiaries in the Company's statement of financial position.

If any such indication exists, the asset's recoverable amount is estimated.

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– *Calculation of recoverable amount*

The recoverable amount of an asset is the greater of its 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. Where an asset does not generate cash inflows largely independent of those from other assets, the recoverable amount is determined for the smallest group of assets that generates cash inflows independently (i.e. a cash-generating unit). A portion of the carrying amount of a corporate asset (for example, head office building) is allocated to an individual cash-generating unit if the allocation can be done on a reasonable and consistent basis, or to the smallest group of cash-generating units if otherwise.

– *Recognition of impairment losses*

An impairment loss is recognized in profit or loss if the carrying amount of an asset, or the cash-generating unit to which it belongs, exceeds its recoverable amount. Impairment losses recognized in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to the cash-generating unit (or group of units) and then, to reduce the carrying amount of the other assets in the unit (or group of units) on a pro rata basis, except that the carrying value of an asset will not be reduced below its individual fair value less costs of disposal (if measurable) or value in use (if determinable).

– *Reversals of impairment losses*

In respect of assets other than goodwill, an impairment loss is reversed if there has been a favourable change in the estimates used to determine the recoverable amount. An impairment loss in respect of goodwill is not reversed.

A reversal of an impairment loss is limited to the asset's carrying amount that would have been determined had no impairment loss been recognized in prior years. Reversals of impairment losses are credited to profit or loss in the year in which the reversals are recognized.

(i) Inventories and other contract costs

(i) *Inventories*

Inventories are assets which are held for sale in the ordinary course of business, in the process of production for such sale or in the form of materials or supplies to be consumed in the production process or in the rendering of services.

Inventories are carried at the lower of cost and net realizable value as follows:

Cost is calculated using the weighted average cost formula and comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

When inventories are sold, the carrying amount of those inventories is recognized as an expense in the period in which the related revenue is recognized.

The amount of any write-down of inventories to net realizable value and all losses of inventories are recognized as an expense in the period the write-down or loss occurs. The amount of any reversal of any write-down of inventories is recognized as a reduction in the amount of inventories recognized as an expense in the period in which the reversal occurs.

(ii) *Other contract costs*

Other contract costs are either the incremental costs of obtaining a contract with a customer or the costs to fulfil a contract with a customer which are not capitalized as inventory (see note 2(i)(i)), property, plant and equipment (see note 2(e)) or intangible assets (see note 2(f)).

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Incremental costs of obtaining a contract are those costs that the Group incurs to obtain a contract with a customer that it would not have incurred if the contract had not been obtained e.g. an incremental sales commission. Incremental costs of obtaining a contract are capitalized when incurred if the costs relate to revenue which will be recognized in a future reporting period and the costs are expected to be recovered. Other costs of obtaining a contract are expensed when incurred.

Costs to fulfil a contract are capitalized if the costs relate directly to an existing contract or to a specifically identifiable anticipated contract; generate or enhance resources that will be used to provide goods or services in the future; and are expected to be recovered. Costs that relate directly to an existing contract or to a specifically identifiable anticipated contract may include direct labour, direct materials, allocations of costs, costs that are explicitly chargeable to the customer and other costs that are incurred only because the Group entered into the contract (for example, payments to sub-contractors). Other costs of fulfilling a contract, which are not capitalized as inventory, property, plant and equipment or intangible assets, are expensed as incurred.

Capitalized contract costs are stated at cost less accumulated amortization and impairment losses. Impairment losses are recognized to the extent that the carrying amount of the contract cost asset exceeds the net of (i) remaining amount of consideration that the Group expects to receive in exchange for the goods or services to which the asset relates, less (ii) any costs that relate directly to providing those goods or services that have not yet been recognized as expenses.

Amortization of capitalized contract costs is charged to profit or loss when the revenue to which the asset relates is recognized. The accounting policy for revenue recognition is set out in note 2(r)(i).

(j) Contract assets and contract liabilities

A contract asset is recognized when the Group recognizes revenue (see note 2(r)(i)) before being unconditionally entitled to the consideration under the payment terms set out in the contract. Contract assets are assessed for expected credit losses (ECL) in accordance with the policy set out in note 2(h)(i) and are reclassified to receivables when the right to the consideration has become unconditional (see note 2(k)).

A contract liability is recognized when the customer pays non-refundable consideration before the Group recognizes the related revenue (see note 2(r)(i)). A contract liability would also be recognized if the Group has an unconditional right to receive non-refundable consideration before the Group recognizes the related revenue. In such cases, a corresponding receivable would also be recognized (see note 2(k)).

For a single contract with the customer, either a net contract asset or a net contract liability is presented. For multiple contracts, contract assets and contract liabilities of unrelated contracts are not presented on a net basis.

When the contract includes a significant financing component, the contract balance includes interest accrued under the effective interest method (see note 2(r)(ii)).

(k) Trade and other receivables

A receivable is recognized when the Group has an unconditional right to receive consideration. A right to receive consideration is unconditional if only the passage of time is required before payment of that consideration is due. If revenue has been recognized before the Group has an unconditional right to receive consideration, the amount is presented as a contract asset.

Trade receivables that do not contain a significant financing component are initially measured at their transaction price. Trade receivables that contain a significant financing component and other receivables are initially measured at fair value plus transaction costs. All receivables are subsequently stated at amortized cost, using the effective interest method and including an allowance for credit losses (see note 2(h)(i)).

Prepayments of the Group represent upfront cash payments made to contract research organizations ("CROs"), hospitals and suppliers for equipment.

Prepayments to CROs and hospitals, which are organizations that provide support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis, will be subsequently recorded as research and development expenses in accordance with the applicable performance requirements within one year or less and therefore are all classified as current assets.

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Prepayments for equipment which are due for transfer to property, plant and equipment and therefore are classified as non-current assets.

(l) Cash and cash equivalents

Cash and cash equivalents comprise cash at bank and on hand, demand deposits with banks, and short-term, highly liquid investments that are readily convertible into known amounts of cash and which are subject to an insignificant risk of changes in value, having been within three months of maturity at acquisition. Cash and cash equivalents are assessed for expected credit losses (ECL) in accordance with the policy set out in note 2(h)(i).

(m) Trade and other payables

Trade and other payables are initially recognized at fair value. Trade and other payables are subsequently stated at amortized cost unless the effect of discounting would be immaterial, in which case they are stated at cost.

(n) Shares issued

Shares issued are classified as equity if they bear discretionary dividends, do not contain any obligations to deliver cash or other financial assets and do not require settlement in a variable number of the Group's equity instruments. Discretionary dividends on such shares issued are recognized as distributions within equity.

A financial liability is recognized if the Group has the obligation to redeem any equity instruments issued on a specific date or at the option of the shareholders (including the options that are only exercisable in case of occurrence of certain contingent triggering events). The liability is recognized and measured at the present value of the exercise price.

(o) Interest-bearing borrowings

Interest-bearing borrowings are measured initially at fair value less transaction costs.

Subsequent to initial recognition, interest-bearing borrowings are stated at amortized cost using the effective interest method. Interest expense is recognized in accordance with the Group's accounting policy for borrowing costs (see note 2(u)).

(p) Employee benefits

(i) Short term employee benefits and contributions to defined contribution retirement plans

Salaries, annual bonuses, paid annual leave, contributions to defined contribution retirement plans and the cost of non-monetary benefits are accrued in the year in which the associated services are rendered by employees. Where payment or settlement is deferred and the effect would be material, these amounts are stated at their present values.

Contribution to appropriate local defined contribution retirement schemes are recognized as an expense in profit or loss as incurred.

(ii) Share-based payments

The fair value of share-based payment awards granted to employees is recognized as an employee cost with a corresponding increase in capital reserves within equity. The fair value is measured at grant date with reference to the price per share in the latest equity financing transaction, taking into account the terms and conditions upon which the share-based payment awards were granted. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the shares, the total estimated fair value of share-based payment awards is spread over the vesting period, taking into account the probability that the shares will vest.

During the vesting period, the number of shares that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognized in prior periods is charged/credited to the profit or loss for the period of the review with a corresponding adjustment to the capital reserves. On vesting date, the amount recognized as an expense is adjusted to reflect the actual number of shares that vest (with a corresponding adjustment to the capital reserve).

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(iii) *Termination benefits*

Termination benefits are recognized at the earlier of when the Group can no longer withdraw the offer of those benefits and when it recognizes restructuring costs involving the payment of termination benefits.

(q) **Income tax**

Income tax for the year comprises current tax and movements in deferred tax assets and liabilities. Current tax and movements in deferred tax assets and liabilities are recognized in profit or loss except to the extent that they relate to items recognized in other comprehensive income or directly in equity, in which case the relevant amounts of tax are recognized in other comprehensive income or directly in equity, respectively.

Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted or substantively enacted at the end of the reporting period, and any adjustment to tax payable in respect of previous years.

Deferred tax assets and liabilities arise from deductible and taxable temporary differences respectively, being the differences between the carrying amounts of assets and liabilities for financial reporting purposes and their tax bases. Deferred tax assets also arise from unused tax losses and unused tax credits.

Apart from certain limited exceptions, all deferred tax liabilities, and all deferred tax assets to the extent that it is probable that future taxable profits will be available against which the asset can be utilized, are recognized. Future taxable profits that may support the recognition of deferred tax assets arising from deductible temporary differences include those that will arise from the reversal of existing taxable temporary differences, provided those differences relate to the same taxation authority and the same taxable entity, and are expected to reverse either in the same period as the expected reversal of the deductible temporary difference or in periods into which a tax loss arising from the deferred tax asset can be carried back or forward. The same criteria are adopted when determining whether existing taxable temporary differences support the recognition of deferred tax assets arising from unused tax losses and credits, that is, those differences are taken into account if they relate to the same taxation authority and the same taxable entity, and are expected to reverse in a period, or periods, in which the tax loss or credit can be utilized.

The limited exceptions to recognition of deferred tax assets and liabilities are those temporary differences arising from goodwill not deductible for tax purposes, the initial recognition of assets or liabilities that affect neither accounting nor taxable profit (provided they are not part of a business combination), and temporary differences relating to investments in subsidiaries to the extent that, in the case of taxable differences, the Group controls the timing of the reversal and it is probable that the differences will not reverse in the foreseeable future, or in the case of deductible differences, unless it is probable that they will reverse in the future.

The carrying amount of a deferred tax asset is reviewed at the end of each reporting period and is reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow the related tax benefit to be utilized. Any such reduction is reversed to the extent that it becomes probable that sufficient taxable profits will be available.

Additional income taxes that arise from the distribution of dividends are recognized when the liability to pay the related dividends is recognized.

Current tax balances and deferred tax balances, and movements therein, are presented separately from each other and are not offset. Current tax assets are offset against current tax liabilities, and deferred tax assets against deferred tax liabilities, if the Company or the Group has the legally enforceable right to set off current tax assets against current tax liabilities and the following additional conditions are met:

- in the case of current tax assets and liabilities, the Company or the Group intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously; or
- in the case of deferred tax assets and liabilities, if they relate to income taxes levied by the same taxation authority on either:
 - the same taxable entity; or
 - different taxable entities, which, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered, intend to realize the current tax assets and settle the current tax liabilities on a net basis or realize and settle simultaneously.

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(r) Revenue and other income

Income is classified by the Group as revenue when it arises from the sale of goods or the provision of services.

Revenue is recognized when control over a product or service is transferred to the customer, at the amount of promised consideration to which the Group is expected to be entitled, excluding those amounts collected on behalf of third parties. Revenue excludes value added tax or other sales taxes.

Further details of the Group’s revenue and other income recognition policies are as follows:

(i) Revenue from contracts with customers

(a) Revenue from license and collaboration agreements

The Group grants licenses of its intellectual property (the “License”) to its customers. The consideration for the License comprises a fixed element (the upfront payment) and variable elements (including but not limited to development milestones and sales-based royalties). The upfront fees are recognized as revenue when customers obtain rights to access the technology. Development milestone payments are included in the transaction price and recognized as revenue throughout the license period when it is highly probable that there will not be a subsequent reversal of a significant amount of revenue. Sales-based royalties are not included in the transaction price until customers make the sales.

(b) Revenue from provision of research and development service

Research and development services are comprised of performance obligations which are capable of being distinct. Accordingly, the transaction price is allocated based on the relative stand-alone selling prices of the services.

For the research and development services that i) the customer simultaneously receives and consumes the benefits provided by the Group’s performance as the Group performs; ii) the Group’s performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or iii) the Group’s performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date, the Group concluded that such services can be identified as a performance obligation satisfied over time. The Group use input methods to recognize revenue on the basis of the Group’s inputs to the satisfaction of a performance obligation relative to the total expected inputs to the satisfaction of that performance obligation.

Otherwise, revenue is recognized at a point in time when the customers accept and can benefit from such service.

(ii) Interest income

Interest income is recognized as it accrues under the effective interest method using the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the gross carrying amount of the financial asset.

(iii) Government grants

Government grants are recognized in the statement of financial position initially when there is reasonable assurance that they will be received and that the Group will comply with the conditions attaching to them. Grants that compensate the Group for expenses incurred are recognized as income in profit or loss on a systematic basis in the same periods in which the expenses are incurred. Grants that compensate the Group for the cost of an asset are recognized as deferred income and subsequently recognized in profit or loss over the useful life of the assets.

(iv) Dividends

Dividend income from unlisted investments is recognized when the shareholder’s right to receive payment is established.

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(s) Translation of foreign currencies

Foreign currency transactions during the Relevant Periods are translated at the foreign exchange rates ruling at the transaction dates. Monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rates ruling at the end of the reporting period. Exchange gains and losses are recognized in profit or loss.

Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the foreign exchange rates ruling at the transaction dates. The transaction date is the date on which the Company initially recognizes such non-monetary assets or liabilities. Non-monetary assets and liabilities denominated in foreign currencies that are stated at fair value are translated using the foreign exchange rates ruling at the dates the fair value was measured.

The results of foreign operations are translated into RMB at the exchange rates approximating the foreign exchange rates ruling at the dates of the transactions. Statement of financial position items are translated into RMB at the closing foreign exchange rates at the end of the reporting period. The resulting exchange differences are recognized in other comprehensive income and accumulated separately in equity in the exchange reserve.

(t) Research and development expenses

Research and development expenses comprise all expenses that are directly attributable to research and development activities or that can be allocated on a reasonable basis to such activities. Expenditure on research activities is recognized as an expense in the period in which it is incurred. Expenditure on development activities is capitalized if the process is technically and commercially feasible and the Group has sufficient resources and the intention to complete development.

(u) Borrowing costs

Borrowing costs that are directly attributable to the acquisition, construction or production of an asset which necessarily takes a substantial period of time to get ready for its intended use or sale are capitalized as part of the cost of that asset. Other borrowing costs are expensed in the period in which they are incurred.

The capitalization of borrowing costs as part of the cost of a qualifying asset commences when expenditure for the asset is being incurred, borrowing costs are being incurred and activities that are necessary to prepare the asset for its intended use or sale are in progress. Capitalization of borrowing costs is suspended or ceases when substantially all the activities necessary to prepare the qualifying asset for its intended use or sale are interrupted or complete.

(v) Related parties

- (a) A person, or a close member of that person’s family, is related to the Group if that person:
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or the Group’s parent.
- (b) An entity is related to the Group if any of the following conditions applies:
 - (i) The entity and the Group are members of the same group (which means that each parent, subsidiary and fellow subsidiary is related to the others).
 - (ii) One entity is an associate or joint venture of the other entity (or an associate or joint venture of a member of a group of which the other entity is a member).
 - (iii) Both entities are joint ventures of the same third party.
 - (iv) One entity is a joint venture of a third entity and the other entity is an associate of the third entity.

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- (v) The entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group.
- (vi) The entity is controlled or jointly controlled by a person identified in (a).
- (vii) A person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity).
- (viii) The entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the Group's parent.

Close members of the family of a person are those family members who may be expected to influence, or be influenced by, that person in their dealings with the entity.

(w) Segment reporting

Operating segments, and the amounts of each segment item reported in the financial statements, are identified from the financial information provided regularly to the Group's most senior executive management for the purposes of allocating resources to, and assessing the performance of, the Group's various lines of business and geographical locations.

Individually material operating segments are not aggregated for financial reporting purposes unless the segments have similar economic characteristics and are similar in respect of the nature of products and services, the nature of production processes, the type or class of customers, the methods used to distribute the products or provide the services, and the nature of the regulatory environment. Operating segments which are not individually material may be aggregated if they share a majority of these criteria.

3 ACCOUNTING JUDGEMENTS AND ESTIMATES

Judgments and estimations used in preparation of the Historical Financial Information are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

Note 27 contain information about the assumptions and their risk factors relating to financial instruments. Other key sources of significant estimation uncertainty are as follows:

(a) Research and development expenses

Development expenses incurred on the Group's pipelines are capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group's intention to complete and the Group's ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development.

Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria met for capitalization. During the Relevant Periods, the Group's development expenditures incurred did not meet these capitalization principles for any products and were expensed as incurred.

(b) Recognition of deferred tax assets

Deferred tax assets in respect of tax losses carried forward and deductible temporary differences are recognized and measured based on the expected manner of realization or settlement of the carrying amount of the relevant assets and liabilities, using tax rates enacted or substantively enacted at the end of each reporting date. In determining the carrying amounts of deferred tax assets, expected taxable profits are estimated which involves a number of assumptions relating to the operating environment of the Group and require a significant level of judgement exercised by the directors. Any change in such assumptions and judgement would affect the carrying amounts of deferred tax assets to be recognized and hence the net profit in future years.

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(c) Depreciation

Property, plant and equipment are depreciated on a straight-line basis over the estimated useful lives of the assets, after taking into account the estimated residual values. The Group reviews the estimated useful lives of the assets regularly in order to determine the amount of depreciation expenses to be recorded during the Relevant Periods. The useful lives are based on the Group’s historical experience with similar assets and taking into account anticipated technological changes. The depreciation expenses for future periods are adjusted if there are significant changes from previous estimates.

4 REVENUE AND SEGMENT REPORTING

(a) Revenue

The principal activities of the Group are the researching and developing service of innovative drugs, manufacturing and commercialization of novel drugs.

(i) Disaggregation of revenue

Disaggregation of revenue from contracts with customers by major service lines is as follows:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	4,463	785,902
Revenue from provision of research and development service	27,859	18,031
	32,322	803,933
	32,322	803,933

Disaggregation of revenue from contracts with customers by the timing of revenue recognition is as follows:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Disaggregated by timing of revenue recognition		
Point in time	4,463	420,919
Over time	27,859	383,014
	32,322	803,933
	32,322	803,933

The Group’s customer base includes two and one customers with whom transactions have exceeded 10% of the Group’s revenues for the year ended December 31, 2021 and 2022, respectively. Revenues from of these customers amounted to approximately RMB31,856,000 and RMB730,037,000 for the year ended December 31, 2021 and 2022 respectively, details of concentrations of credit risk arising from these three customers are set out in note 27(a).

(ii) Revenue expected to be recognized in the future arising from contracts with customers in existence at the reporting date.

The aggregate amount of the transaction price allocated to performance obligations that are unsatisfied were RMB1,308,402,000 and RMB892,444,000 as at December 31, 2021 and 2022, respectively, which is expected to occur over the next 12 to 15 months (2021: next 12 to 24 months).

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(b) Segment reporting

(i) Segment information

The Group manages its businesses as a whole by the most senior executive management for the purposes of resource allocation and performance assessment. The Group’s chief operating decision maker is the chief executive officer of the Group who reviews the Group’s consolidated results of operations in assessing performance of and making decisions about allocations to this segment.

Accordingly, no reportable segment information is presented.

(ii) Geographic information

The following table sets out information about the geographical location of (i) the Group’s revenue from external customers and (ii) the Group’s property, plant and equipment, right-of-use assets, intangible assets and other non-current assets (“specified non-current assets”). The geographical location of customers is based on the location at which the customers are registered. The geographical location of the specified non-current assets is based on the physical location of the asset, in the case of property, plant and equipment, right-of-use assets and the location of the operation to which they are allocated, in the case of intangible assets and other non-current assets.

Revenues from external customers

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
The PRC (Place of domicile)	20,385	56,488
The USA	–	730,037
Other countries	11,937	17,408
	<u>32,322</u>	<u>803,933</u>

Non-current assets

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
The PRC	512,082	660,310
The USA	2,535	519
	<u>514,617</u>	<u>660,829</u>

5 OTHER NET INCOME/(EXPENSE)

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Interest income from bank deposits	806	1,417
Net foreign exchange gains/(losses)	16,877	(31,944)
Government grants	16,716	20,254
Net (loss)/gain on disposal of property, plant and equipment	(5)	5,418
Net realized and unrealized gain on financial assets measured at FVPL	359	513
Others	90	(26)
	<u>34,843</u>	<u>(4,368)</u>

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6 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging:

(a) Finance costs

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Interest expenses on bank loans	1,574	2,893
Interest expenses on other borrowings from Kelun Pharmaceutical	90,209	108,301
Interest expenses on financial instruments issued to investors	27,295	40,943
Interest expenses on lease liabilities	164	5,605
	<u>119,242</u>	<u>157,742</u>
Less: interest expenses capitalized into construction in progress	<u>(6,651)</u>	<u>(8,928)</u>
	<u><u>112,591</u></u>	<u><u>148,814</u></u>

The borrowing costs have been capitalized at a rate of 4.35% for the year ended December 31, 2021 and 2022.

(b) Staff costs

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Salaries, wages, bonuses and other benefits	331,505	360,001
Contributions to defined contribution retirement plan	15,081	16,789
Equity-settled share-based payment expenses (<i>note 24</i>)	6,496	19,811
	<u>353,082</u>	<u>396,601</u>

Staff costs includes remuneration of directors, supervisors and senior management (note 8 and note 29(a)).

Pursuant to the relevant labor rules and regulations in the PRC, the Company and its subsidiaries in the PRC participate in defined contribution retirement benefit schemes (the “Schemes”) organized by the local government authorities whereby the Company and its subsidiaries in the PRC are required to make contributions to the Schemes based on certain percentages of the eligible employee’s salaries. The local government authorities are responsible for the entire pension obligations payable to the retired employees.

The Group has no other material obligation for payment of other retirement benefits beyond the above contributions.

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(c) **Other items**

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Amortization cost of intangible assets	298	2,640
Depreciation charge		
– property, plant and equipment (note 12)	19,329	23,328
– right-of-use assets (note 13)	3,287	41,396
Auditors’ remuneration		
– audit services	108	504
[REDACTED]	–	9,288
Research and development expenses*	727,670	845,984
Cost of sales#	20,525	276,828

* During the year ended December 31, 2021 and 2022, research and development expenses include RMB279,462,000 and RMB316,042,000, respectively relating to staff costs and depreciation and amortization expenses, which are also included in the respective total amounts disclosed separately above or in the note 6(b) for each of these types of expenses.

During the year ended December 31, 2021 and 2022, cost of sales includes RMB13,269,000 and RMB79,163,000 respectively relating to staff costs and depreciation and amortization expenses, which are also included in the respective total amounts disclosed separately above or in note 6(b) for each of these types of expenses.

7 INCOME TAX IN THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS

(a) Taxation in the consolidated statement of profit or loss represents:

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Current tax		
Provision for the year		
– The PRC Corporate Income Tax	–	–
– Withholding Tax	–	48,735
	–	48,735
	–	48,735

(i) **PRC Corporate Income Tax**

Effective from January 1, 2008, the PRC statutory income tax rate is 25% under the PRC Corporate Income Tax Law. The Group’s subsidiaries in the PRC are subject to PRC income tax at 25% unless otherwise specified.

According to the PRC Corporate Income Tax Law and its relevant regulations, entities that qualified as high-technology enterprise are entitled to a preferential income tax rate of 15%. The Company obtained its certificate of high-technology enterprise on December 3, 2020 and is entitled to preferential income tax of 15% from 2020 to 2022.

(ii) **Withholding Tax**

Pursuant to US Income Tax laws and regulations and the agreement between the government of the People’s Republic of China and the USA for avoidance of double taxation and the prevention of fiscal evasion with respect to taxes on income (中華人民共和國政府和美利堅合眾國政府關於對所得避免雙重徵稅和防止偷漏稅的協定), a 10% US federal withholding tax is charged on royalties paid pursuant to license and collaboration agreements entered between the Company and a US company.

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(b) Reconciliation between tax expense and accounting loss at applicable tax rates

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Loss before taxation	(889,795)	(567,364)
Notional tax on loss before taxation, calculated at the rates applicable to profits in the countries concerned	(219,278)	(140,221)
Effect of preferential income tax rates	80,842	52,570
Tax effect of non-deductible expenses	1,005	15,724
Tax effect of unused tax losses not recognized	197,072	65,786
Tax effect of bonus deduction for research and development expenses	(63,735)	–
Tax effect of interest expenses arising from financial instrument issued to investors	4,094	6,141
Withholding tax	–	48,735
Actual tax expense	–	48,735

- (i) An additional 75% of qualified research and development expenses incurred is allowed to be deducted from taxable income under the PRC income tax laws and its relevant regulations. An additional 100% of qualified research and development expenses is allowed to be deducted from taxable income since October 1, 2022.

8 DIRECTORS’ AND SUPERVISORS’ EMOLUMENTS

Directors’ and supervisors’ emoluments are as follows:

	Year ended December 31, 2021					Total RMB’000
	Salaries, allowances and benefits in kind RMB’000	Discretionary bonuses RMB’000	Retirement scheme contributions RMB’000	Share-based payments RMB’000 (note 1)		
Executive Directors						
Mr. Wang Jingyi (王晶翼)	5,241	3,125	165	(12)		8,519
Non-executive Directors						
Mr. Liu Gexin (劉革新)	–	–	–	–		–
Mr. Liu Sichuan (劉思川)	–	–	–	–		–
Mr. Feng Hao (馮昊) (appointed in March 2021)	–	–	–	114		114
Ms. Yang Qiuyan (楊秋豔) (resigned in March 2021) (note 5)	137	35	1	21		194
Mr. Chen Deguang (陳得光)	3,419	373	7	480		4,279
Supervisors						
Ms. Song Hongmei (宋宏梅) (appointed in March 2021)	1,157	279	6	172		1,614
Mr. Wan Peng (萬鵬) (appointed in March 2021)	–	–	–	–		–
Mr. Lai Degui (賴德貴) (appointed in March 2021)	–	–	–	114		114

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	Year ended December 31, 2021				
	Salaries, allowances and benefits in kind <i>RMB'000</i>	Discretionary bonuses <i>RMB'000</i>	Retirement scheme contributions <i>RMB'000</i>	Share-based payments <i>RMB'000</i> <i>(note 1)</i>	Total <i>RMB'000</i>
Mr. Chang Jianhui (常建輝) (resigned in March 2021) <i>(note 5)</i>	73	24	1	19	117
Ms. Zhou Yingzi (周英姿) (resigned in March 2021) <i>(note 5)</i>	191	48	9	27	275
Ms. Wang Jing (汪靜) (resigned in March 2021) <i>(note 5)</i>	106	–	1	(34)	73
	<u>10,324</u>	<u>3,884</u>	<u>190</u>	<u>901</u>	<u>15,299</u>

	Year ended December 31, 2022				
	Salaries, allowances and benefits in kind <i>RMB'000</i>	Discretionary bonuses <i>RMB'000</i>	Retirement scheme contributions <i>RMB'000</i>	Share-based payments <i>RMB'000</i> <i>(note 1)</i>	Total <i>RMB'000</i>
Executive Directors					
Mr. Wang Jingyi (王晶翼)	3,512	578	154	(83)	4,161
Mr. Ge Junyou (葛均友) (appointed in February 2022)	2,004	800	31	380	3,215
Non-executive Directors					
Mr. Liu Gexin (劉革新)	–	–	–	–	–
Mr. Liu Sichuan (劉思川)	–	–	–	–	–
Mr. Feng Hao (馮昊)	–	–	–	136	136
Mr. Li Dongfang (李東方) (appointed in February 2022)	–	–	–	–	–
Mr. Chen Deguang (陳得光) (resigned in February 2022) <i>(note 5)</i>	272	80	4	74	430
Mr. Zeng Xuebo (曾學波) (appointed in July 2022)	–	–	–	–	–
Mr. Zhou Zejian (周澤劍) (appointed in February 2022 and resigned in July 2022) <i>(note 5)</i>	–	–	–	–	–
Supervisors					
Ms. Song Hongmei (宋宏梅)	1,495	420	8	206	2,129
Mr. Wan Peng (萬鵬)	–	–	–	–	–
Mr. Lai Degui (賴德貴)	–	–	–	136	136
Ms. Qing Yan (卿燕) (appointed in March 2022)	1,017	312	6	122	1,457

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	Year ended December 31, 2022				
	Salaries, allowances and benefits in kind <i>RMB’000</i>	Discretionary bonuses <i>RMB’000</i>	Retirement scheme contributions <i>RMB’000</i>	Share-based payments <i>RMB’000</i> <i>(note 1)</i>	Total <i>RMB’000</i>
Ms. Yang Qiuyan (楊秋豔) (appointed in March 2022)	686	200	6	97	989
Ms. Liao Yihong (廖益虹) (appointed in February 2022)	—	—	—	—	—
	<u>8,986</u>	<u>2,390</u>	<u>209</u>	<u>1,068</u>	<u>12,653</u>

Note 1: These represent the estimated value of restricted share units granted to the directors and supervisors under the Company’s restricted share unit scheme. The value of these restricted share units is measured according to the Group’s accounting policies for share-based payment transactions as set out in note 2(p) and, in accordance with that policy, includes adjustments to reverse amounts accrued in previous years where grants of equity instruments are forfeited prior to vesting. The details of share-based payment, including the principal terms and number of options granted, are disclosed in note 24.

Note 2: During the years ended December 31, 2021 and 2022, no emoluments was paid by the Group to the directors, supervisors or any of the five highest paid individuals set out in note 9 below as an inducement to join or upon joining the Group or as compensation for loss of office. No director or supervisor has waived for agreed to waive any emoluments during the Relevant Periods.

Note 3: During the year ended December 31, 2021 and 2022, Mr. Liu Gexin, Mr. Liu Sichuan, Mr. Wan Peng and Ms. Liao Yihong were not paid directly by the Group but received remuneration from the Group’s holding company, in respect of their services to the larger group which includes the Group. No apportionment has been made as the qualifying services provided by them to the Group are incidental to their responsibilities to the larger group.

Note 4: Dr. Zheng Qiang (鄭強), Dr. Tu Wenwei (涂文偉), Dr. Li Yuedong (李越冬) and Dr. Jin Jinping (金錦萍) were appointed as independent non-executive Directors of the Company on February 15, 2023.

Note 5: Both Ms. Yang Qiuyan and Mr. Chen Deguang resigned as non-executive directors due to internal work adjustments while Mr. Zhou Zejian resigned as a non-executive director due to personal reasons during the Relevant Periods. Mr. Chang Jianhui, Ms. Zhou Yingzi and Ms. Wang Jing resigned as supervisors due to internal work adjustments.

9 INDIVIDUALS WITH HIGHEST EMOLUMENTS

For the year ended December 31, 2021 and 2022, of the five individuals with the highest remuneration, 2 and 1 are directors whose remuneration are disclosed in note 8.

The aggregate remuneration in respect of the remaining individuals are as follows:

	Year ended December 31,	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Salaries and other emoluments	10,102	10,682
Discretionary bonuses	1,209	3,137
Share-based payments	931	15,896
Retirement scheme contributions	99	443
	<u>12,341</u>	<u>30,158</u>

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The remuneration of the above individuals with the highest remuneration are within the following bands:

	Year ended December 31,	
	2021	2022
	Number of Individuals	Number of Individuals
HKD3,500,001 – HKD4,000,000	1	–
HKD4,500,001 – HKD5,000,000	–	1
HKD5,000,001 – HKD5,500,000	1	–
HKD6,000,001 – HKD6,500,000	1	–
HKD7,000,001 – HKD7,500,000	–	1
HKD8,000,001 – HKD8,500,000	–	1
HKD15,000,001 – HKD15,500,000	–	1

10 OTHER COMPREHENSIVE INCOME

	Year ended December 31,					
	2021			2022		
	Before-tax amount RMB’000	Tax expense RMB’000	Net-of-tax amount RMB’000	Before-tax amount RMB’000	Tax expense RMB’000	Net-of-tax amount RMB’000
Exchange differences on translation of financial statements of an overseas subsidiary	(3,910)	–	(3,910)	13,988	–	13,988

11 LOSS PER SHARE

(a) Basic loss per share

The calculation of basic loss per share is based on the loss for the year attributable to ordinary equity shareholders of the Company and the weighted average number of ordinary shares in issue during the Relevant Periods, calculated as follows.

(i) Loss attributable to ordinary equity shareholders of the Company used in basic loss per share calculation:

	Year ended December 31,	
	2021 RMB’000	2022 RMB’000
Loss for the year attributable to ordinary equity shareholders	(889,795)	(616,099)
Allocation of loss for the year attributable to financial instruments issued to investors	67,245	68,000
Loss for the year attributable to ordinary equity shareholders of the Company for the purpose of basic loss per share	<u>(822,550)</u>	<u>(548,099)</u>

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(ii) *Weighted average number of shares*

	Year ended December 31,	
	2021	2022
Issued ordinary shares at January 1	76,688,750	107,369,609
Effect of issuance of new shares	23,325,536	–
Effect of the financial instruments issued to investors	(7,558,477)	(11,850,609)
	92,455,809	95,519,000
Weighted average number of ordinary shares at December 31	92,455,809	95,519,000

Effect of the financial instruments issued to investors (see note 22) represents the weighted average number of ordinary shares of the Company that are subject to redemption and excluded from the calculation of the basic loss per share for the Relevant Periods.

(b) **Diluted loss per share**

The 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. For the year ended December 31, 2021 and 2022, the Company had the financial instruments issued to investors as financial liabilities which are potential ordinary shares (see note 22). As the Group incurred losses for the year ended December 31, 2021 and 2022, the potential ordinary shares 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 Relevant Periods were the same as basic loss per share of the respective period.

12 PROPERTY, PLANT AND EQUIPMENT (“PPE”)

(a) **Reconciliation of carrying amount**

The Group

	Machinery and equipment <i>RMB’000</i>	Furniture, fixtures and others <i>RMB’000</i>	Vehicles <i>RMB’000</i>	Leasehold improvements <i>RMB’000</i>	Construction in progress <i>RMB’000</i>	Total <i>RMB’000</i>
Cost:						
At January 1, 2021	114,455	31,023	–	391	142,117	287,986
Purchases	53,076	3,036	324	–	140,243	196,679
Exchange adjustments	(441)	(32)	(9)	(9)	–	(491)
Disposals	(1,252)	(20)	–	–	–	(1,272)
	165,838	34,007	315	382	282,360	482,902
At December 31, 2021 and January 1, 2022	165,838	34,007	315	382	282,360	482,902
Purchases	30,849	14,175	–	–	93,211	138,235
Transfer from construction in progress	13,733	–	–	13,252	(26,985)	–
Exchange adjustments	990	6	16	35	–	1,047
Disposals	(36,757)	(1,286)	(331)	–	–	(38,374)
	174,653	46,902	–	13,669	348,586	583,810
At December 31, 2022	174,653	46,902	–	13,669	348,586	583,810

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	Machinery and equipment	Furniture, fixtures and others	Vehicles	Leasehold improvements	Construction in progress	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Accumulated depreciation						
At January 1, 2021	(29,602)	(2,252)	–	(117)	–	(31,971)
Charge for the year	(16,416)	(2,823)	(64)	(26)	–	(19,329)
Exchange adjustments	397	23	1	3	–	424
Disposals	146	7	–	–	–	153
At December 31, 2021 and						
January 1, 2022	(45,475)	(5,045)	(63)	(140)	–	(50,723)
Charge for the year	(18,050)	(3,166)	(18)	(2,094)	–	(23,328)
Exchange adjustments	(942)	(6)	(3)	(24)	–	(975)
Disposals	20,517	964	84	–	–	21,565
At December 31, 2022						
	<u>(43,950)</u>	<u>(7,253)</u>	<u>–</u>	<u>(2,258)</u>	<u>–</u>	<u>(53,461)</u>
Net book value:						
At December 31, 2022	<u>130,703</u>	<u>39,649</u>	<u>–</u>	<u>11,411</u>	<u>348,586</u>	<u>530,349</u>
At December 31, 2021	<u>120,363</u>	<u>28,962</u>	<u>252</u>	<u>242</u>	<u>282,360</u>	<u>432,179</u>

The Company

	Machinery and equipment	Furniture, fixtures and others	Leasehold improvements	Construction in progress	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cost:					
At January 1, 2021	95,201	29,607	–	95,102	219,910
Purchases	53,076	3,036	–	118,857	174,969
Disposals	(1,252)	(20)	–	–	(1,272)
At December 31, 2021 and					
January 1, 2022	147,025	32,623	–	213,959	393,607
Purchases	30,849	14,175	–	89,305	134,329
Transfer from construction in progress	13,733	–	13,252	(26,985)	–
Disposals	(16,974)	(82)	–	–	(17,056)
At December 31, 2022					
	<u>174,633</u>	<u>46,716</u>	<u>13,252</u>	<u>276,279</u>	<u>510,880</u>
Accumulated depreciation					
At January 1, 2021	(13,170)	(1,302)	–	–	(14,472)
Charge for the year	(14,567)	(2,706)	–	–	(17,273)
Disposals	146	7	–	–	153
At December 31, 2021 and					
January 1, 2022	(27,591)	(4,001)	–	–	(31,592)
Charge for the year	(18,048)	(3,152)	(1,841)	–	(23,041)
Disposals	1,709	70	–	–	1,779
At December 31, 2022					
	<u>(43,930)</u>	<u>(7,083)</u>	<u>(1,841)</u>	<u>–</u>	<u>(52,854)</u>

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	Machinery and equipment <i>RMB’000</i>	Furniture, fixtures and others <i>RMB’000</i>	Leasehold improvements <i>RMB’000</i>	Construction in progress <i>RMB’000</i>	Total <i>RMB’000</i>
Net book value:					
At December 31, 2022	130,703	39,633	11,411	276,279	458,026
At December 31, 2021	119,434	28,622	–	213,959	362,015

13 RIGHT-OF-USE ASSETS

The analysis of the net book value of right-of-use assets by class of underlying asset is as follows:

The Group

	Land use rights <i>RMB’000</i>	Properties leased for own use <i>RMB’000</i>	Machinery and equipment leased for own use <i>RMB’000</i>	Total <i>RMB’000</i>
Cost:				
At January 1, 2021	44,938	2,639	–	47,577
Additions	–	1,026	–	1,026
Exchange adjustments	–	(54)	–	(54)
At December 31, 2021 and January 1, 2022	44,938	3,611	–	48,549
Additions	–	21,077	96,893	117,970
Disposals	(1,278)	(3,434)	–	(4,712)
Exchange adjustments	–	146	–	146
At December 31, 2022	43,660	21,400	96,893	161,953
Accumulated depreciation				
At January 1, 2021	(3,293)	–	–	(3,293)
Charge for the year	(1,058)	(2,229)	–	(3,287)
Exchange adjustments	–	18	–	18
At December 31, 2021 and January 1, 2022	(4,351)	(2,211)	–	(6,562)
Charge for the year	(875)	(8,223)	(32,298)	(41,396)
Disposals	183	3,434	–	3,617
Exchange adjustments	–	(137)	–	(137)
At December 31, 2022	(5,043)	(7,137)	(32,298)	(44,478)
Net book value:				
At December 31, 2022	38,617	14,263	64,595	117,475
At December 31, 2021	40,587	1,400	–	41,987

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The Company

	Land use rights RMB’000	Properties leased for own use RMB’000	Machinery and equipment leased for own use RMB’000	Total RMB’000
Cost:				
At January 1, 2021	22,342	267	–	22,609
Additions	–	1,026	–	1,026
At December 31, 2021 and January 1, 2022	22,342	1,293	–	23,635
Additions	–	20,500	96,893	117,393
Disposals	(1,278)	(995)	–	(2,273)
At December 31, 2022	<u>21,064</u>	<u>20,798</u>	<u>96,893</u>	<u>138,755</u>
Accumulated depreciation				
At January 1, 2021	(1,488)	–	–	(1,488)
Charge for the year	(605)	(666)	–	(1,271)
At December 31, 2021 and January 1, 2022	(2,093)	(666)	–	(2,759)
Charge for the year	(422)	(7,367)	(32,298)	(40,087)
Disposals	183	995	–	1,178
At December 31, 2022	<u>(2,332)</u>	<u>(7,038)</u>	<u>(32,298)</u>	<u>(41,668)</u>
Net book value:				
At December 31, 2022	<u>18,732</u>	<u>13,760</u>	<u>64,595</u>	<u>97,087</u>
At December 31, 2021	<u>20,249</u>	<u>627</u>	<u>–</u>	<u>20,876</u>

The analysis of expense items in relation to leases recognized in the Group’s profit or loss is as follows:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Depreciation charge of right-of-use assets by class of underlying asset:		
Land use rights, carried at depreciated cost	1,058	875
Properties leased for own use, carried at depreciated cost	2,229	8,223
Machinery and equipment leased for own use, carried at depreciated cost	–	32,298
	<u>3,287</u>	<u>41,396</u>
Interest expenses on lease liabilities (note 6(a))	164	5,605
Expense relating to short-term leases	43,069	845

Details of total cash outflow for leases and the maturity analysis of lease liabilities are set out in notes 18(d) and 21, respectively.

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14 OTHER NON-CURRENT ASSETS

The Group

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Prepayments for property, plant and equipment	39,965	9,826
	<u>39,965</u>	<u>9,826</u>

The Company

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Prepayments for property, plant and equipment	39,611	8,876
	<u>39,611</u>	<u>8,876</u>

15 INVENTORIES AND OTHER CONTRACT COSTS

The Group and the Company

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Raw materials	45,590	48,643
Low-value consumables	5,134	3,993
	<u>50,724</u>	<u>52,636</u>
Contract costs	27,983	–
	<u>78,707</u>	<u>52,636</u>

All of the contract costs are expected to be recovered within one year.

16 CONTRACT LIABILITIES

The Group and the Company

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Receipts in advance	109,038	163,976
	<u>109,038</u>	<u>163,976</u>

Movements in contract liabilities

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Balance at January 1	–	109,038
Decrease in contract liabilities as a result of recognizing revenue during the year that was included in the contract liabilities at the beginning of the year	–	(109,038)
Increase in contract liabilities as a result of receipts in advance	109,038	163,976
	<u>109,038</u>	<u>163,976</u>
Balance at December 31	<u>109,038</u>	<u>163,976</u>

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All of contract liabilities are expected to be recognized as income within one year.

17 TRADE AND OTHER RECEIVABLES

The Group

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Trade receivables	146	–
Other receivables	2,165	1,846
Value Added Tax (“VAT”) recoverable	45,557	40,785
Prepayments	30,657	56,028
	<u>78,525</u>	<u>98,659</u>

The Company

	As at December 31,	
	<i>2021</i>	<i>2022</i>
	<i>RMB’000</i>	<i>RMB’000</i>
Trade receivables	146	–
Other receivables	1,810	1,800
VAT recoverable	41,482	35,832
Prepayments	30,657	56,028
	<u>74,095</u>	<u>93,660</u>

(a) Ageing analysis

As at the end of each reporting period, the ageing analysis of trade receivables (which are included in trade and other receivables), based on the invoice date and net of loss allowance, is as follows:

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Within 3 months (inclusive)	<u>146</u>	<u>–</u>

Trade debtors are due within 30 days from the date of billing. Further details on the Group’s credit policy are set out in note 27(a).

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18 CASH AND CASH EQUIVALENTS AND OTHER CASH FLOW INFORMATION

(a) Cash and cash equivalents comprise:

The Group

		As at December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Cash at bank		118,421	119,221
Less: restricted bank deposits	(i)	<u>(36,628)</u>	<u>(26,261)</u>
Cash and cash equivalents in the consolidated statements of financial position		<u>81,793</u>	<u>92,960</u>

The Company

		As at December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Cash at bank		116,552	116,623
Less: restricted bank deposits	(i)	<u>(36,628)</u>	<u>(26,261)</u>
Cash and cash equivalents in the statements of financial position		<u>79,924</u>	<u>90,362</u>

(i) Restricted bank deposits are pledged deposits for issuance of bills payable. The pledged deposits will be released upon the settlement of relevant bills payable.

(b) Reconciliation of loss before taxation to cash (used in)/generated from operations:

		Year ended December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Loss before taxation		(889,795)	(567,364)
Adjustments for:			
Depreciation of property, plant and equipment	6(c)	19,329	23,328
Depreciation of right-of-use assets	6(c)	3,287	41,396
Amortization of intangible assets	6(c)	298	2,640
Finance costs	6(a)	112,591	148,814
Net loss/(gain) on disposal of property, plant and equipment	5	5	(5,418)
Net realized and unrealized gain on financial assets measured at FVPL	5	(359)	(513)
Equity-settled share-based payment expenses	6(b)	6,496	19,811
Net foreign exchange (gains)/losses	5	(16,877)	31,944
Changes in working capital:			
(Increase)/decrease in inventories and other contract costs	15	(37,282)	26,071
Decrease/(increase) in trade and other receivables		239	(20,134)
Increase in amounts due from related parties		(20,791)	(20,991)
(Increase)/decrease in restricted bank deposits	18(a)	(36,628)	10,367
Increase in trade and other payables		90,671	50,572
Increase/(decrease) in amounts due to related parties		173,836	(17,573)
Increase in contract liabilities		<u>109,038</u>	<u>6,203</u>
Net cash used in operating activities		<u>(485,942)</u>	<u>(270,847)</u>

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(c) Reconciliation of liabilities arising from financing activities

The table below details changes in the Group’s liabilities from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are liabilities for which cash flows were, or future cash flows will be, classified in the Group’s consolidated statements of cash flows as cash flows from financing activities.

	Bank loans <i>RMB'000</i> <i>(note 20)</i>	Other borrowings from Kelun Pharmaceutical <i>RMB'000</i> <i>(note 20)</i>	Financial instruments issued to investors <i>RMB'000</i> <i>(note 22)</i>	Lease liabilities <i>RMB'000</i> <i>(note 21)</i>	Total <i>RMB'000</i>
At January 1, 2021	60,000	1,988,424	–	3,916	2,052,340
Changes from financing cash flows:					
Proceeds from new bank loans	30,000	–	–	–	30,000
Repayment of bank loans	(60,000)	–	–	–	(60,000)
Proceeds from other borrowings from Kelun Pharmaceutical	–	195,484	–	–	195,484
Repayment of other borrowings from Kelun Pharmaceutical	–	(10,000)	–	–	(10,000)
Proceeds from issuance of shares with preferential rights	–	–	511,783	–	511,783
Capital element of lease rentals paid	–	–	–	(1,990)	(1,990)
Interest element of lease rentals paid	–	–	–	(164)	(164)
Interest paid	(1,574)	(38,251)	–	–	(39,825)
Total changes from financing cash flows	(31,574)	147,233	511,783	(2,154)	625,288
Exchange adjustments	–	(14,034)	–	(37)	(14,071)
Other changes:					
Increase in lease liabilities from entering into new leases during the year	–	–	–	1,026	1,026
Interest expenses <i>(note 6(a))</i>	1,574	90,209	27,295	164	119,242
Transfer from trade and other payables	–	146,135	–	–	146,135
Total other changes	1,574	236,344	27,295	1,190	266,403
At December 31, 2021	30,000	2,357,967	539,078	2,915	2,929,960
	Bank loans <i>RMB'000</i> <i>(note 20)</i>	Other borrowings from Kelun Pharmaceutical <i>RMB'000</i> <i>(note 20)</i>	Financial instruments issued to investors <i>RMB'000</i> <i>(note 22)</i>	Lease liabilities <i>RMB'000</i> <i>(note 21)</i>	Total <i>RMB'000</i>
At January 1, 2022	30,000	2,357,967	539,078	2,915	2,929,960
Changes from financing cash flows:					
Proceeds from new bank loans	115,000	–	–	–	115,000
Repayment of bank loans	(45,000)	–	–	–	(45,000)
Proceeds from other borrowings from Kelun Pharmaceutical	–	248,000	–	–	248,000
Capital element of lease rentals paid	–	–	–	(1,621)	(1,621)
Interest element of lease rentals paid	–	–	–	(34)	(34)
Interest paid	(2,893)	–	–	–	(2,893)
Total changes from financing cash flows	67,107	248,000	–	(1,655)	313,452

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	Bank loans <i>RMB'000</i> <i>(note 20)</i>	Other borrowings from Kelun Pharmaceutical <i>RMB'000</i> <i>(note 20)</i>	Financial instruments issued to investors <i>RMB'000</i> <i>(note 22)</i>	Lease liabilities <i>RMB'000</i> <i>(note 21)</i>	Total <i>RMB'000</i>
Exchange adjustments	–	25,099	–	61	25,160
Other changes:					
Increase in lease liabilities from entering into new leases during the year	–	–	–	117,970	117,970
Interest expenses (note 6(a))	2,893	108,301	40,943	5,605	157,742
Termination of lease arrangement	–	–	–	(1,340)	(1,340)
Transfer from trade and other payables	–	51,420	–	–	51,420
Total other changes	<u>2,893</u>	<u>159,721</u>	<u>40,943</u>	<u>122,235</u>	<u>325,792</u>
At December 31, 2022	<u>100,000</u>	<u>2,790,787</u>	<u>580,021</u>	<u>123,556</u>	<u>3,594,364</u>

(d) Total cash outflow for leases

	Year ended December 31,	
	2021 <i>RMB'000</i>	2022 <i>RMB'000</i>
Within operating cash flows	403	762
Within financing cash flows	2,154	1,655
	<u>2,557</u>	<u>2,417</u>

19 TRADE AND OTHER PAYABLES

The Group

	As at December 31,	
	2021 <i>RMB'000</i>	2022 <i>RMB'000</i>
Trade payables	98,341	123,259
Other payables	6,029	3,059
Bills payable	33,641	27,777
Accrued payroll and benefits	44,723	86,608
Other taxes payable	2,522	2,702
	<u>185,256</u>	<u>243,405</u>

The Company

	As at December 31,	
	2021 <i>RMB'000</i>	2022 <i>RMB'000</i>
Trade payables	81,167	113,601
Other payables	5,690	2,785
Bills payable	33,641	27,777
Accrued payroll and benefits	43,116	83,107
Other taxes payable	2,522	2,674
	<u>166,136</u>	<u>229,944</u>

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As at the end of each reporting period, the ageing analysis of trade payables and bills payable (which are included in trade and other payables), based on the invoice date, is as follows:

The Group

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Within 1 year	131,142	149,663
1 to 2 years	346	642
2 to 3 years	320	307
More than 3 years	174	424
	131,982	151,036
	131,982	151,036

The Company

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Within 1 year	113,968	140,005
1 to 2 years	346	642
2 to 3 years	320	307
More than 3 years	174	424
	114,808	141,378
	114,808	141,378

20 BANK LOANS AND OTHER BORROWINGS

The analysis of the carrying amount of bank loans and other borrowings is as follows:

The Group

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Current		
Guaranteed bank loans (i)	30,000	100,000
Other borrowings from Kelun Pharmaceutical (ii)	2,357,967	2,790,787
	2,387,967	2,890,787
	2,387,967	2,890,787

The Company

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Current		
Guaranteed bank loans (i)	30,000	100,000
Other borrowings from Kelun Pharmaceutical (ii)	2,289,252	2,719,449
	2,319,252	2,819,449
	2,319,252	2,819,449

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(i) Bank loans

As at December 31, 2021, the bank loan of RMB30,000,000 with interest rate of 3.85% per annum were guaranteed by Mr. Liu Gexin.

As at December 31, 2022, the bank loan of RMB100,000,000 with interest rate of 3.75% per annum were guaranteed by Kelun Pharmaceutical.

(ii) Other borrowings from Kelun Pharmaceutical

As at December 31, 2021 and 2022, other borrowings of RMB2,357,967,000 and RMB2,790,787,000 from Kelun Pharmaceutical were interest-bearing at 4.35% per annum, unsecured and payment on demand. This related party balance was settled in January 2023 pursuant to a share subscription and debt-to-equity swap agreement, for details, please refer to note 32.

21 LEASE LIABILITIES

As at the end of each reporting period, the lease liabilities were repayable as follows:

The Group

	As at December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	1,663	82,264
After 1 year but within 2 years	250	41,148
After 2 years but within 5 years	572	144
After 5 years	430	–
	<u>1,252</u>	<u>41,292</u>
	<u>2,915</u>	<u>123,556</u>

The Company

	As at December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	739	82,072
After 1 year but within 2 years	250	40,942
After 2 years but within 5 years	572	–
After 5 years	430	–
	<u>1,252</u>	<u>40,942</u>
	<u>1,991</u>	<u>123,014</u>

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22 FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

In 2021, the Company entered into an investment agreement with certain independent investors, pursuant to which, these investors paid in the aggregate, RMB511,783,000 (or USD equivalent) and subscribed for the Company’s share capital of RMB11,851,000 (referred as “Series A Investments”).

The investors of the Series A Investments are entitled to the same voting rights and dividend rights as other founding shareholders of the Company, and these Series A Investments will be automatically transferred to equity upon [REDACTED]. Certain key preferential rights issued to the investors of the Series A Investments are summarized as follows:

Liquidation preference

In the event of any liquidation or dissolution of the Company, the investors of the Series A Investments shall be entitled to receive the amount equal to the aggregate of the original issue price plus per annum interest 8% calculated on a simple basis and all declared but unpaid dividends (the “Priority Liquidation Amount”). After the Priority Liquidation Amount is paid off, if the Company still has net assets legally available for distribution, the investors of the Series A Investments shall be entitled to the residual assets according to its shareholding on a pro rata basis.

Investors’ redemption rights

The investors of the Series A Investments would have the right but not the obligation to request the Company and/or the actual controller of the Company to purchase all or part of the shares of the Company held by them, upon the occurrence of any of the specified contingent events, including but not limited to:

- (i) a qualified [REDACTED] of the Company does not consummate by the 3rd anniversary of the closing date;
- (ii) the Company, the existing shareholders or the actual controller of the Company have materially breached any term of the transaction documents.

The redemption price of each share shall equal to the aggregate of the original issue price plus per annum interest 8% calculated on a simple basis for the period from the payment date of the consideration up to the redemption date, plus all declared but unpaid dividends.

Upon the occurrence of any of the deemed liquidation events, such as a merger, reorganization, acquisition, or other similar transaction or series of transactions that result in the change of control of the Company, the investors of the Series A Investments would have the right but not the obligation to request the Company and/or the existing shareholders of the Company to purchase all or part of the shares of the Company held by the investors. The redemption price applicable to the occurrence of a deemed liquidation event, shall equal to the aggregate of the Priority Liquidation Amount, plus the proportionate share of the Company’s residual assets legally available for distribution after paying the Priority Liquidation Amount to such investors according to the shares redeemed by them then.

Presentation and classification

As the occurrence of the specified redemption triggering events such as no qualified [REDACTED] of the Company consummated by the specified date and change of control, is beyond the Company’s control, the Company recognized financial liabilities for its obligation to buy back the shares, i.e. the financial instruments issued to investors. The financial liabilities are measured at the present value of the redemption amount. The changes in the carrying amount of the financial liabilities were recorded in profit or loss as “finance costs”.

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The movements of the financial liabilities recognized for the financial instruments issued to investors during the Relevant Periods are set out below:

The Group and the Company

	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
At beginning of the year	–	539,078
Issuance of shares with preferential rights	511,783	–
Changes in carrying amount of financial instruments issued to investors	27,295	40,943
	<u>539,078</u>	<u>580,021</u>

23 DEFERRED INCOME

The Group

	As at December 31,	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Government grants	10,678	10,678
	<u>10,678</u>	<u>10,678</u>

The Company

	As at December 31,	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Government grants	7,678	7,678
	<u>7,678</u>	<u>7,678</u>

Deferred income of the Group mainly represents government grants received for the construction of property, plant and equipment, which would be recognized as “other net income” on a straight-line basis over the expected useful lives of the relevant assets.

24 EQUITY SETTLED SHARE-BASED TRANSACTIONS

Restricted Share Unit Scheme

Pursuant to a written shareholders’ resolution of the Company passed on May 29, 2020, a Restricted Share Unit (“RSU”) Scheme (“the Scheme”) was adopted for purpose of providing incentives to eligible employees of the Group. The RSUs would be granted to eligible employees of the Group through four companies, which act as the share-based payment vehicles, at a discounted price. Subject to grantees’ service to the Group through the applicable vesting date, the RSUs shall vest after 4 years from the date of grant. If employments of the grantees are terminated before the RSUs become vested, the unvested RSUs shall be repurchased at the purchase price paid by the grantees when the RSUs were granted plus reasonable interest. Each RSU entitles the holder to own one ordinary share of the Company. Under the Scheme, the maximum number of RSUs granted shall not exceed 30,000,000 units (equivalent to 30,000,000 ordinary shares of the Company).

The Group granted 21,319,000 RSUs to certain directors and employees of the Group at a discounted price ranging from RMB1 to RMB1.18 per unit on August 24, 2020 (the Grant Date 2020), the date on which employees accepted the terms and conditions of the RSUs offered by the Group.

The Group granted 5,290,000 RSUs to certain directors and employees of the Group at a discounted price at RMB1.30 per unit on December 30, 2022 (the Grant Date 2022), the date on which employees accepted the terms and conditions of the RSUs offered by the Group.

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When the Group received cash from grantees for purchasing the RSUs granted, the Group recognized the par value of shares underlying these RSUs in share capital and the difference between cash received and the par value of shares in capital reserves.

Fair value of RSUs

The fair value of services received in return for RSUs granted is measured by reference to the fair value of RSUs granted. The estimate of the fair value of RSUs granted at the Grant Date 2020 and the Grant Date 2022 are respectively RMB3 per unit and RMB51.7 per unit, which were determined with reference to the price per share in equity financing transaction with third parties of the Company close to the grant dates.

(a) Movements in the number of RSUs are as follows:

	Number of RSUs	
	Year ended December 31,	
	2021	2022
At January 1	20,760,750	15,691,250
Granted during the year	–	5,290,000
Forfeited during the year	(5,069,500)	(2,710,000)
	15,691,250	18,271,250
At December 31	15,691,250	18,271,250

(b) Equity-settled share-based payment expenses recognized in the consolidated statements of profit or loss during the Relevant Periods:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Research and development expenses	4,025	17,759
Administrative expenses	2,471	2,052
	6,496	19,811
	6,496	19,811

25 INCOME TAX IN THE CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(a) Current taxation in the consolidated statements of financial position represents:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Provision for PRC Corporate Income Tax for the year	–	–
Withholding tax for the year	–	48,735
Withholding tax paid	–	(48,735)
	–	–
	–	–

(b) Deferred tax assets and liabilities not recognized:

In accordance with the accounting policy set out in note 2(q), as at December 31, 2021 and 2022, the Group has not recognized deferred tax assets in respect of cumulative tax losses of RMB4,003,675,000 and RMB4,425,977,000, respectively, as it is not probable that future taxable profits against which the losses can be utilized before expiries.

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Pursuant to the relevant laws and regulations in the PRC and US, the unrecognized tax losses at the end of each reporting period will expire in the following years:

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
2022	77	–
2023	794	794
2024	4,527	4,527
2026	2,124	2,124
After 2026	3,996,153	4,418,532
	<u>4,003,675</u>	<u>4,425,977</u>

All the tax losses of the Company can be carried forward for a maximum period of ten years pursuant to Notice No. 76 issued by the Ministry of Finance and the State Administration of Taxation of the PRC on July 11, 2018, since the Company obtained its certificate of the High Technology Enterprise on December 3, 2020.

All the tax losses of the Group’s PRC subsidiary can be carried forward for a maximum period of five years.

All the tax losses of the Group’s subsidiary in the USA can be carried forward for a maximum period of twenty years.

26 CAPITAL, RESERVES AND DIVIDENDS

(a) Movements in components of equity

The reconciliation between the opening and closing balances of each component of the Group’s consolidated equity is set out in the consolidated statement of changes in equity. Details of the changes in the Company’s individual components of equity between the beginning and the end of each reporting period are set out below:

The Company

	<i>Note</i>	Share capital	Capital reserves	Accumulated losses	Total
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Balance at January 1, 2021		76,689	41,561	(1,755,845)	(1,637,595)
Changes in equity for 2021:					
Loss for the year		–	–	(808,417)	(808,417)
Issuance of new shares	26(c)	18,830	3,198	–	22,028
Issuance of shares with preferential rights	22	11,851	499,932	–	511,783
Recognition of financial liabilities recognized for preferential rights issued to investors	22	–	(511,783)	–	(511,783)
Equity-settled share-based payment	24	–	6,496	–	6,496
Balance at December 31, 2021		<u>107,370</u>	<u>39,404</u>	<u>(2,564,262)</u>	<u>(2,417,488)</u>
	<i>Note</i>	Share capital	Capital reserves	Accumulated losses	Total
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Balance at January 1, 2022		107,370	39,404	(2,564,262)	(2,417,488)
Changes in equity for 2022:					
Loss for the year		–	–	(574,424)	(574,424)
Equity-settled share-based payment	24	–	19,811	–	19,811
Balance at December 31, 2022		<u>107,370</u>	<u>59,215</u>	<u>(3,138,686)</u>	<u>(2,972,101)</u>

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(b) Dividends

The directors of the Company did not propose the payment of any dividend during the Relevant Periods.

(c) Share capital

As at December 31, 2021 and 2022, the Company has 116,050,609 shares registered with par value of RMB1 for each share, respectively.

	2021		2022	
	No. of shares	Amount RMB’000	No. of shares	Amount RMB’000
Registered share capital				
At January 1	104,200,000	104,200	116,050,609	116,051
Financial instrument issued to investors	11,850,609	11,851	–	–
At December 31	<u>116,050,609</u>	<u>116,051</u>	<u>116,050,609</u>	<u>116,051</u>

	2021		2022	
	No. of shares	Amount RMB’000	No. of shares	Amount RMB’000
Ordinary shares, issued and fully paid:				
At January 1	76,688,750	76,689	107,369,609	107,370
Issuance of new shares (i)	18,830,250	18,830	–	–
Financial instrument issued to investors	11,850,609	11,851	–	–
At December 31	<u>107,369,609</u>	<u>107,370</u>	<u>107,369,609</u>	<u>107,370</u>

(i) This amount represents the par value of shares underlying the RSUs received in 2021 (see note 24). During 2021, the share-based payment vehicles paid RMB22,028,000 to the Company in exchange of 18,830,250 shares of the Company.

(d) Nature and purpose of reserves

(i) Capital reserves

The capital reserves comprise the following:

- the amount represents the difference between the consideration received and the par value of the issued shares of the Company;
- the amount related to merger reserves resulted from business combinations in 2020 involving entities under common control;
- the portion of the grant date fair value of unlocked RSUs granted to employees of the Group that has been recognized in accordance with the accounting policy adopted for share-based payments in note 2(p); and
- the amount of financial liabilities arising from Series A investments as set out in note 22.

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ACCOUNTANTS’ REPORT

(ii) Exchange reserves

The exchange reserves comprise all foreign exchange differences arising from the translation of the financial statements of foreign operation with functional currency other than RMB. The reserves are dealt with in accordance with the accounting policies set out in note 2(s).

(e) Capital management

The Group’s primary objectives when managing capital are to safeguard the Group’s ability to continue as a going concern, so that it can continue to provide returns for shareholders and benefits for other stakeholders, by pricing services commensurately with the level of risk and by securing access to finance at a reasonable cost.

The Group actively and regularly reviews and manages its capital structure to maintain a balance between the higher shareholder returns that might be possible with higher levels of borrowings and the advantages and security afforded by a sound capital position, and makes adjustments to the capital structure in light of changes in economic conditions.

The Group monitors its capital structure on the basis of an adjusted liability-to-asset ratio. For this purpose, adjusted liabilities include bank loans and lease liabilities but exclude financial instruments issued to investors and other borrowings from Kelun Pharmaceutical.

The Group’s adjusted liability-to-asset ratio at December 31, 2021 and 2022 was as follows:

	<i>Note</i>	As at December 31,	
		2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Current liabilities:			
Bank loans	20	30,000	100,000
Lease liabilities	21	1,663	82,264
		31,663	182,264
Non-current liabilities:			
Lease liabilities	21	1,252	41,292
Adjusted liabilities		32,915	223,556
Total assets		812,958	993,145
Adjusted liability-to-asset ratio		4.05%	22.51%

27 FINANCIAL RISK MANAGEMENT AND FAIR VALUES OF FINANCIAL INSTRUMENTS

Exposure to credit, liquidity, interest rate and currency risks arises in the normal course of the Group’s business.

The Group’s exposure to these risks and the financial risk management policies and practices used by the Group to manage these risks are described below.

(a) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to the Group. The Group’s credit risk is primarily attributable to trade receivables. The Group’s exposure to credit risk arising from cash and cash equivalents is limited because the counterparties are banks for which the Group considers to have low credit risk.

The Group also expects that there is no significant credit risk associated with other receivables and amounts due from related parties since the counterparties to these financial assets have no history of default.

The Group does not provide any guarantees which would expose the Group to credit risk.

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Trade receivables

The Group’s exposure to credit risk is influenced mainly by the individual characteristics of each customer. As at December 31, 2021, all of the total trade receivables were due from the Group’s five largest customers.

Individual credit evaluations are performed on all customers requiring credit over a certain amount. These take into account the customer’s past payment history, financial position and other factors. Trade receivables are due within 30 days from the date of billing. Normally, the Group does not obtain collateral from customers.

The Group measures loss allowances for trade receivables at an amount equal to lifetime ECLs.

As the Group’s historical credit loss experience does not indicate significantly different loss patterns for different customer segments, the loss allowance based on past due status is not further distinguished between the Group’s different customer bases. At December 31, 2021 and 2022, the Group did not provide any loss allowance for trade receivables.

(b) Liquidity risk

The Group’s policy is to regularly monitor its liquidity requirements and its compliance with lending covenants, to ensure that it maintains sufficient reserves of cash to meet its liquidity requirements in the short and longer term.

The following tables show the remaining contractual maturities at the end of each reporting period of the Group’s non-derivative financial liabilities, which are based on contractual undiscounted cash flows (including interest payments computed using contractual rates or, if floating, based on rates current at the end of the reporting period) and the earliest date the Group can be required to pay:

The Group

	As at December 31, 2021				Total	Carrying amount at December 31, 2021
	Contractual undiscounted cash outflow	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years		
Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years			
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Bank loans and other borrowings	2,490,663	–	–	–	2,490,663	2,387,967
Lease liabilities	1,736	298	660	440	3,134	2,915
Trade and other payables	185,256	–	–	–	185,256	185,256
Amounts due to related parties	221,912	–	–	–	221,912	221,912
Financial instruments issued to investors	580,021	–	–	–	580,021	539,078
	<u>3,479,588</u>	<u>298</u>	<u>660</u>	<u>440</u>	<u>3,480,986</u>	<u>3,337,128</u>

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	As at December 31, 2022					Carrying amount at December 31, 2022 RMB’000
	Contractual	undiscounted cash outflow			Total	
	More than 1 year but less than 2 years RMB’000	More than 2 years but less than 5 years RMB’000	More than 5 years RMB’000			
	Within 1 year or on demand RMB’000					
Bank loans and other borrowings	3,013,748	-	-	-	3,013,748	2,890,787
Lease liabilities	86,087	43,103	147	-	129,337	123,556
Trade and other payables	243,405	-	-	-	243,405	243,405
Amounts due to related parties	206,908	-	-	-	206,908	206,908
Financial instruments issued to investors	620,963	-	-	-	620,963	580,021
	<u>4,171,111</u>	<u>43,103</u>	<u>147</u>	<u>-</u>	<u>4,214,361</u>	<u>4,044,677</u>

(c) Interest rate risk

The Group’s interest-bearing financial instruments at variable rates as at December 31, 2021 and 2022 are the cash at bank, and the cash flow interest risk arising from the change of market interest rate on these balances of relatively short maturity is not considered significant. The Group’s majority interest-bearing financial instruments at fixed interest rates as at December 31, 2021 and 2022 are bank loans, other borrowings from Kelun Pharmaceutical, financial instruments issued to investors and lease liabilities that are measured at amortized cost, and the change of market interest rate does not expose the Group to significant interest risk.

Overall speaking, the Group’s exposure to interest rate risk is not significant.

(d) Currency risk

The Group is exposed to currency risk primarily through sales and purchases which give rise to cash and cash equivalents and amounts due to related parties that are denominated in a foreign currency, i.e., a currency other than the functional currency of the operations to which the transactions relate. The currencies giving rise to this risk is primarily United States dollars. The Group manages this risk as follows:

(i) Exposure to currency risk

The following table details the Group’s exposure at the end of each reporting period to currency risk arising from recognized assets or liabilities denominated in a currency other than the functional currency of the entity to which they relate. For presentation purposes, the amounts of the exposure are shown in RMB, translated using the spot rate at the period end date.

USD	As at December 31,	
	2021 RMB’000	2022 RMB’000
Cash and cash equivalents	57,371	5,905
Amounts due to related parties	(182,836)	(199,724)
Other borrowings from Kelun Pharmaceutical	(271,732)	(296,831)
	<u>(397,197)</u>	<u>(490,650)</u>

(ii) Sensitivity analysis

The following table indicates the instantaneous change in the Group’s loss before taxation and other components of consolidated equity that would arise if foreign exchange rates to which the Group has significant exposure at the end of the reporting period had changed at that date, assuming all other risk variables remained constant.

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	As at December 31, 2021		As at December 31, 2022	
	Increase/(decrease) in foreign exchange rates	Effect on loss before tax and accumulated losses RMB’000	Increase/(decrease) in foreign exchange rates	Effect on loss before tax and accumulated losses RMB’000
USD	10%	(39,720)	10%	(49,065)
	(10%)	39,720	(10%)	49,065

Results of the analysis as presented in the above table represent an aggregation of the instantaneous effects on each of the Group entities’ loss before tax and equity measured in the respective functional currencies, translated into RMB at the exchange rate ruling at the end of the reporting period for presentation purposes.

The sensitivity analysis assumes that the change in foreign exchange rates had been applied to re-measure those financial instruments held by the Group which expose the Group to foreign currency risk at the end of the reporting period. The analysis is performed on the same basis during the reporting period.

(e) Fair value measurement

(i) Financial assets and liabilities measured at fair value

Fair value hierarchy

IFRS 13, *Fair value measurement* categorises fair value measurements into a three-level hierarchy. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs i.e. unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2 valuations: Fair value measured using Level 2 inputs i.e., observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available;
- Level 3 valuations: Fair value measured using significant unobservable inputs.

During the year ended December 31, 2021 and 2022, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3. The Group’s policy is to recognize transfers between levels of fair value hierarchy as at the end of the Relevant Periods in which they occur.

(ii) Fair value of financial assets and liabilities carried at other than fair value

The carrying amounts of the Group’s financial instruments carried at cost or amortized cost were not materially different from their fair values as at December 31, 2021 and 2022.

28 COMMITMENTS

Commitments outstanding at December 31, 2021 and 2022 not provided for in the financial statements were as follows:

	As at December 31,	
	2021 RMB’000	2022 RMB’000
Contracted for construction in progress	86,332	70,151

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29 MATERIAL RELATED PARTY TRANSACTIONS

(a) Key management personnel remuneration

Remuneration for key management personnel of the Group, including amounts paid to the Company’s directors and supervisors as disclosed in note 8 and certain of the highest paid employees as disclosed in note 9, is as follows:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Short-term employee benefits	26,306	27,061
Contributions to defined contribution retirement plan	283	545
Equity-settled share-based payment expenses	1,789	10,726
	<u>28,378</u>	<u>38,332</u>

Total remuneration is included in “staff costs” (see note 6(b)).

(b) Identify of related parties

Name of party	Relationship with the Group
Mr. Liu GeXin (劉革新)	Ultimate controlling shareholder
Kelun Pharmaceutical (四川科倫藥業股份有限公司) together with its subsidiaries (“Kelun Group”)	Immediate holding company
Sichuan Kelun Medicine & Trade Group Co., Ltd. (“Kelun Medicine & Trade”) (四川科倫醫藥貿易集團有限公司) together with its subsidiaries (“Kelun Medicine & Trade Group”)	Company controlled by the ultimate controlling shareholder
Sichuan Kelun Doosan Biotechnology Co., Ltd. (“Kelun Doosan”) (四川科倫鬥山生物技術有限公司)	A joint venture of Kelun Pharmaceutical

(c) Significant related party transactions

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Trade related:		
Provision of R&D services to:		
Kelun Group	19,919	16,190
Procurement of R&D services from:		
Kelun Group	74,147	15,666
Transfer of R&D projects to:		
Kelun Group	–	39,761
Sales of low-value consumables to:		
Kelun Group	1,040	148
Disposal of PPE to:		
Kelun Group	1,065	16,036

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	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Procurement of goods from:		
Kelun Group	1,644	7,270
Kelun Medicine & Trade Group	9,838	25,605
	<u>11,482</u>	<u>32,875</u>
Procurement of PPE from:		
Kelun Group	36,990	7,217
Kelun Medicine & Trade Group	–	620
	<u>36,990</u>	<u>7,837</u>
Short-term lease expense to Kelun Group	<u>42,892</u>	<u>–</u>
Receiving other miscellaneous services from:		
Kelun Group	5,732	13,093
Kelun Medicine & Trade Group	–	143
	<u>5,732</u>	<u>13,236</u>
Non-trade related:		
Amounts borrowed from:		
Kelun Group	<u>341,619</u>	<u>299,420</u>
Amounts repaid to:		
Kelun Group	<u>48,251</u>	<u>–</u>
Interest expense on borrowings from Kelun Pharmaceutical	<u>90,209</u>	<u>108,301</u>
Interest expense on lease liabilities to Kelun Group	<u>63</u>	<u>5,571</u>
 (d) Balances with related parties		
The Group		
	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due from:		
– Trade Related:		
Kelun Group	22,583	61,635
Kelun Medicine & Trade Group	–	165
	<u>22,583</u>	<u>61,800</u>
– Non-trade related:		
Kelun Group	<u>105</u>	<u>–</u>
	<u>22,688</u>	<u>61,800</u>

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	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due to:		
– Trade Related:		
Kelun Group	193,020	176,308
Kelun Medicine & Trade Group	279	113
	<u>193,299</u>	<u>176,421</u>
– Non-trade related:		
Kelun Group	26,494	29,063
Kelun Doosan	2,119	1,424
	<u>28,613</u>	<u>30,487</u>
	<u>221,912</u>	<u>206,908</u>
Non-trade related:		
Other borrowings from:		
Kelun Pharmaceutical	2,357,967	2,790,787
	<u>2,357,967</u>	<u>2,790,787</u>
Trade related:		
Lease liabilities due to:		
Kelun Group	1,340	122,854
	<u>1,340</u>	<u>122,854</u>
The Company		
	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due from:		
– Trade Related:		
Kelun Group	22,583	61,635
Kelun Medicine & Trade Group	–	165
	<u>22,583</u>	<u>61,800</u>
– Non-trade related:		
A subsidiary of the Company	16,202	27,213
Kelun Group	105	–
	<u>16,307</u>	<u>27,213</u>
	<u>38,890</u>	<u>89,013</u>

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	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due to:		
– Trade Related:		
A subsidiary of the Company	182,836	199,723
Kelun Group	193,020	176,308
Kelun Medicine & Trade Group	279	113
	<u>376,135</u>	<u>376,144</u>
– Non-trade related:		
Kelun Group	–	155
Kelun Doosan	2,119	1,424
	<u>2,119</u>	<u>1,579</u>
	<u>378,254</u>	<u>377,723</u>
Non-trade related:		
Other borrowings from:		
Kelun Pharmaceutical	2,289,252	2,719,449
	<u>2,289,252</u>	<u>2,719,449</u>
Trade related:		
Lease liabilities due to:		
Kelun Group	1,340	122,854
	<u>1,340</u>	<u>122,854</u>

The outstanding balances of lease liabilities arising from the leasing arrangement with the Kelun Pharmaceutical are included in “Lease liabilities” (note 21).

The balances of non-trade related amount due to related parties are unsecured, interest-free and payable on demand. All the non-trade balances with related parties as at December 31, 2022 had been fully settled as at date of this report.

As at December 31, 2021 and 2022, other borrowings of RMB2,357,967,000 and RMB2,790,787,000 from Kelun Pharmaceutical were interest-bearing at 4.35% per annum, unsecured and payment on demand.

(e) Guarantee provided by related parties

As disclosed in note 20, the bank loans of RMB30,000,000 and RMB100,000,000 as at December 31, 2021 and 2022, respectively, were guaranteed by related parties. All of the above-mentioned loans guaranteed by related parties had been repaid in February 2023.

30 IMMEDIATE AND ULTIMATE CONTROLLING PARTY

At December 31, 2021 and 2022, the directors consider the immediate parent of the Group to be Kelun Pharmaceutical which is incorporated in the PRC and ultimate controlling party of the Group to be Mr. Liu Gexin. Kelun Pharmaceutical is listed on the Shenzhen Stock Exchange and produces financial statements available for public use.

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31 POSSIBLE IMPACT OF AMENDMENTS, NEW STANDARDS AND INTERPRETATIONS

Up to the date of issue of this report, the IASB has issued a number of amendments, and a new standards and interpretations which are not yet effective for the accounting period beginning on January 1, 2022 and which have not been adopted in the Historical Financial Information as follows:

	Effective for accounting periods beginning on or after
IFRS 17, <i>Insurance contracts</i> and related amendments	January 1, 2023
Amendments to IAS 1 and IFRS Practice Statement 2, <i>Disclosure of accounting policies</i>	January 1, 2023
Amendments to IFRS 4, <i>Extension of the temporary exemption from applying IFRS 9</i>	January 1, 2023
Amendments to IAS 8, <i>Definition of accounting estimates</i>	January 1, 2023
Amendments to IAS 12, <i>Deferred tax related to assets and liabilities arising from a single transaction</i>	January 1, 2023
Amendments to IAS 1, <i>Classification of liabilities as current or non-current</i>	January 1, 2024
Amendments to IAS 1, <i>Non-current Liabilities with Covenants</i>	January 1, 2024
Amendments to IFRS 16, <i>Lease Liability in a Sale and Leaseback</i>	January 1, 2024
Amendments to IFRS 10 and IAS 28, <i>Sale or contribution of assets between an investor and its associate or joint venture</i>	To be determined

The Group is in the process of making an assessment of what the impact of these amendments, new standards and interpretations is expected to be in the period of initial application. So far, the Group has concluded that the adoption of them is unlikely to have a significant impact on the Group’s results of operations and financial position.

32 SUBSEQUENT EVENTS

On January 3, 2023, the Company, Kelun Pharmaceutical and the other then Shareholders of the Company entered into a share subscription and debt-to-equity swap agreement, pursuant to which Kelun Pharmaceutical agreed to further subscribe for an aggregate of 51,255,685 shares at a total subscription price of RMB2,650,000,000, among which RMB2,500,000,000 was settled through debt-to-equity swap and RMB150,000,000 was settled by cash on January 16, 2023.

On January 3, 2023, a series of share subscription agreements (“Series B Share Subscription Agreements”) were entered into among, the Company, Kelun Pharmaceutical, the other then Shareholders and other investors. Pursuant to the Series B Share Subscription Agreements, the investors agreed to subscribe for an aggregate of 26,076,205 shares at a total subscription price of RMB1,348,181,000 which was completed in February 2023.

33 INTERESTS IN SUBSIDIARIES

The Company

The carrying amounts of interests in subsidiaries of the Company is listed below:

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Interests in subsidiaries	372,707	410,604

For the particulars of subsidiaries, please refer to note 1(b).

Subsequent Financial Statements

No audited financial statements have been prepared by the Company or any of its subsidiaries comprising the Group in respect of any period subsequent to December 31, 2022.

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

TAXATION AND FOREIGN EXCHANGE

1. TAXATION OF SECURITY HOLDERS

The taxation of income and capital gains of holders of H Shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of H Shares are resident or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current laws and practices, is subject to change and does not constitute legal or tax 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, some of which may be subject to special regulation. Accordingly, you should consult your own tax adviser 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 and may have retrospective effect.

This discussion does not address any aspects of PRC or Hong Kong taxation other than income tax, capital tax, stamp duty and estate duty. Prospective investors are urged to consult their financial advisers regarding the PRC, Hong Kong and other tax consequences of owning and disposing of H Shares.

A. The PRC Taxation

Taxation on Dividends

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》), which was latest amended on August 31, 2018 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was latest amended on December 18, 2018 (hereinafter collectively referred to as the “**IIT Law**”), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty.

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), (the “**Arrangement**”) which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《第五議定書》) issued by the State Administration of Taxation (“**SAT**”), which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, such

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benefits shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Agreement, unless it can be confirmed that the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Enterprise Investors

In accordance with the Corporate Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) issued by NPC on March 16, 2007, implemented on January 1, 2008 and subsequently amended on February 24, 2017 and December 29, 2018 and the Implementation Provisions of the Corporate Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, came into effect on January 1, 2008 and amended in 2019 (hereinafter collectively referred to as the “CIT Law”), a non-resident enterprise is generally subject to a 10% corporate income tax on PRC-sourced income (including dividends received from a PRC resident enterprise), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due.

The Circular of the SAT on Issues Relating to the Withholding and Remitting of Corporate Income Tax by PRC Resident Enterprises on Dividends Distributed to Overseas Non-Resident Enterprise Shareholders of H Shares (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No. 897), which was issued and implemented by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a uniform rate of 10% on the dividends of 2008 and onwards that it distributes to overseas non-resident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Corporate Income Tax on Dividends Derived by Non-resident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》) (Guo Shui Han [2009] No. 394), which was issued by the SAT and implemented on July 24, 2009, further provides that any PRC-resident enterprise listed on overseas stock exchanges must withhold and remit corporate income tax at a uniform rate of 10% on dividends of 2008 and onwards that it distributes to the shareholders of non-resident enterprises. Such tax rates may be further modified pursuant to the tax treaty or arrangement that China has entered into with the relevant jurisdictions, where applicable.

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Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《第五議定書》) issued by the SAT, which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Agreement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC are entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

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Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《關於全面推開營業稅改徵增值稅試點的通知》) (Cai Shui [2016] No. 36) (hereinafter referred to as “**Notice 36**”), which was implemented on May 1, 2016, entities and individuals engaged in the sale services, intangible assets or real estate in the PRC are subject to Value-added Tax (hereinafter referred to as “**VAT**”) and “engaged in the sale services in the PRC” means that the seller or buyer of the taxable services is located in the PRC. Notice 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT.

According to these regulations, if the holder is a non-resident individual, the PRC VAT is exempted from the sale or disposal of H shares; if the holder is a non-resident enterprise and the H-share buyer is an individual or entity located outside China, the holder is not necessarily required to pay the PRC VAT, but if the H-share buyer is an individual or entity located in China, the holder may be required to pay the PRC VAT.

However, in view of no clear regulations, whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares, there is still uncertainty in the interpretation and application of the above provisions. At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge (hereinafter collectively referred to as “**Local Additional Tax**”), which shall usually equal to 12% of the VAT payable (if any).

Income Tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular of the Ministry of Finance and the State Administration of Taxation on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《財政部、國家稅務總局關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi [1998] No. 61) issued by the Ministry of Finance (“**MOF**”) and the SAT on March 30, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. The SAT has not expressly stated whether it will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended IIT Law.

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However, on December 31, 2009, the MOF, the SAT and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》) (Cai Shui [2009] No. 167), which came into effect on the same date, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the SSE and the SZSE shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) (Cai Shui [2010] No. 70) jointly issued and implemented by such departments on November 10, 2010). As of the Latest Practicable Date, no aforesaid provisions have expressly provided that individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges.

Enterprise Investors

In accordance with the CIT Law, a non-resident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

Pursuant to the Stamp Tax Law of the PRC (《中華人民共和國印花稅法》) issued on June 10, 2021 and effective on July 1, 2022, entities and individuals that issue taxable certificates and conduct securities transactions within the territory of China shall pay stamp duty, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this Document, there is no estate duty currently levied in the PRC.

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Taxation Policy of Shanghai-Hong Kong Stock Connect

Under the Announcement on Continued Implementation of Individual Income Tax Policies Relating to Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect and Mainland and Hong Kong Mutual Recognition of Funds (MOF Announcement [2019] No. 93) (《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》(財政部公告2019年第93號)) came into effect on December 5, 2019, from December 5, 2019 to December 31, 2022, gains on price difference from transfer of shares derived by mainland individual investors through investment into shares listed on the Hong Kong Stock Exchange via the Shanghai-Hong Kong Stock Connect shall be exempted from individual income tax. Under the Notice of the Ministry of Finance, the State Administration of Taxation and the China Securities Regulatory Commission on the Tax Policies Related to the Pilot Program of the Shanghai-Hong Kong Stock Connect (《財政部、國家稅務總局、中國證券監督管理委員會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》) which came into effect on November 17, 2014, for dividends and bonus obtained by mainland individual investors investing in H shares listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect, the H-share companies shall apply to China Securities Depository and Clearing Co., Ltd. (hereinafter referred to as "CSDCC") for provision by CSDCC to the H-share companies register of mainland individual investors, and the H-share companies shall withhold individual income tax at the rate of 20%.

Under the Notice of the Ministry of Finance, the State Administration of Taxation and the China Securities Regulatory Commission on the Tax Policies Related to the Pilot Program of the Shanghai-Hong Kong Stock Connect (Cai Shui [2014] No. 81) (《財政部、國家稅務總局、中國證券監督管理委員會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》(財稅[2014]81號)) which came into effect on November 17, 2014, gains on price difference from transfer of shares derived by mainland enterprise investors 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. In particular, EIT will be exempted according to law for dividend and bonus income obtained by mainland resident enterprises which hold H shares for at least 12 consecutive months. For dividend and bonus income obtained by mainland enterprises, the H-share companies will not withhold dividend and bonus income tax for mainland enterprises. The tax payable shall be declared and paid by the enterprises themselves.

Taxation Policy of Shenzhen-Hong Kong Stock Connect

Under the Announcement on Continued Implementation of Individual Income Tax Policies Relating to Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect and Mainland and Hong Kong Mutual Recognition of Funds (MOF Announcement [2019] No. 93) (《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》(財政部公告2019年第93號)) came into effect on December 5, 2019, personal income tax will be temporarily exempted for transfer spread income derived from investment by mainland individual investors in

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stocks listed on the Hong Kong Stock Exchange through Shenzhen-Hong Kong Stock Connect from December 5, 2019 to December 31, 2022. Under the Notice on the Tax Policies Related to the Pilot Program of the Shenzhen-Hong Kong Stock Connect (Cai Shui [2016] No. 127) (《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》(財稅[2016]127號)) which came into effect on December 5, 2016, for dividends and bonus income obtained by mainland individual investors investing in H shares listed on the Hong Kong Stock Exchange through Shenzhen-Hong Kong Stock Connect, the H-share companies shall apply to CSDCC for provision by CSDCC to the H-share companies register of mainland individual investors, and personal income tax shall be withheld by H-share companies at the tax rate of 20%.

Under the Notice on the Tax Policies Related to the Pilot Program of the Shenzhen-Hong Kong Stock Connect (Cai Shui [2016] No. 127) (《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》(財稅[2016]127號)) which came into effect on December 5, 2016, transfer spread income derived by mainland enterprises 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, EIT will be exempted according to law for dividend and bonus income obtained by mainland resident enterprises which hold H shares for at least 12 consecutive months. For dividend and bonus income obtained by mainland enterprises, the H-share companies will not withhold dividend and bonus income tax for mainland enterprises. The tax payable shall be declared and paid by the enterprises themselves.

B. Hong Kong Taxation

Taxation on Dividends

No tax is payable in Hong Kong in respect of dividends paid by our Company.

Profits Tax

Hong Kong profits tax will not be payable by any Shareholders (other than Shareholders carrying on a trade, profession or business in Hong Kong and holding the H Shares for trading purposes) on any capital gains made on the sale or other disposal of the Shares. Trading gains from the sale of 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 chargeable to Hong Kong income tax rates of 16.5% on corporations and 15.0% on individuals, unless such gains are chargeable under the respective half-rates of 8.25% and 7.5% that may apply for the first HK\$2 million of assessable profits for years of assessment beginning on or after 1 April 2018. Gains from sales of H Shares effected on the Stock Exchange will be considered by the Hong Kong Inland Revenue Department to be derived from or arise in Hong Kong. Shareholders should take advice from their own professional advisers as to their particular tax position.

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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.

AFRC Transaction Levy

The AFRC Transaction Levy was applicable to all sale and purchase of securities at 0.00015% per side with effect from January 1, 2022, which will be regarded as one of the transaction costs.

Estate Duty

Hong Kong estate duty was abolished effective from February 11, 2006. No Hong Kong estate duty is payable by Shareholders in relation to the Shares owned by them upon death.

2. PRINCIPAL TAXATION OF OUR COMPANY IN THE PRC

Enterprise Income Tax

According to the EIT Law, the PRC enterprise income tax rate is 25%, which is in line with the applicable tax rates for foreign-invested enterprises and foreign enterprises.

According to the Administrative Measures for Determination of High and New Tech Enterprises 《高新技術企業認定管理辦法》 promulgated by the Ministry of Science and Technology, the MOF and the SAT on April 14, 2008, amended on January 29, 2016 and became effective on January 1, 2016, enterprises recognized as high and new technology enterprises may apply for a preferential enterprise income tax rate of 15% in accordance with the relevant provisions of the EIT Law. According to the Notice Regarding the Promotion of the Income Tax Policy for Technologically Advanced Service Enterprises to the Whole Country (《關於將技術先進型服務企業所得稅政策推廣至全國實施的通知》) promulgated by the MOF, the SAT, MOFCOM, MOST and NDRC on November 2, 2017, and effective on January 1, 2018, the enterprise income tax shall be levied on certified technologically advanced service enterprises at a reduced tax rate of 15% across the country. The portion of the employee educational expenses of a certified technologically advanced service enterprise not exceeding 8% of its total salaries and wages shall be allowed to be deducted in calculating its taxable income; and the excessive portion shall be allowed to be carried forward to the subsequent tax years for deduction.

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Value-added Tax

According to the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》), which was promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017 (the “**Regulations on VAT**”), and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the MOF, came into effect on December 25, 1993 and latest amended on October 28, 2011, all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall be subject to value-added tax. All enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 0%, 6%, 11% and 17% for the different goods it sells and different services it provides, unless otherwise provided. According to the Circular of the Ministry of Finance and the State Administration of Foreign Exchange on Adjusting Value-added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》), which was issued on April 4, 2018 and came into effect on May 1, 2018, where a tax payer engages in a taxable sales activity for the value-added tax purpose or imports goods, the previous applicable 17% and 11% tax rates are adjusted to be 16% and 10%, respectively. According to the Announcement on Deepening Policies in relation to Value-added Tax Reform (《關於深化增值稅改革有關政策的公告》) which was promulgated on March 20, 2019 and became effective on April 1, 2019, where a tax payer engages in a taxable sales activity for the value-added tax purpose or imports goods, the VAT rates are reduced to 13% and 9%, respectively.

FOREIGN EXCHANGE

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The SAFE, with the authorization of the People’s Bank of China (“**PBOC**”), is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The principal regulations governing foreign currency exchange in China are Regulations for Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Control Regulations**”) which was promulgated by the State Council on January 29, 1996, became effective on April 1, 1996 and was subsequently amended on January 14, 1997 and August 5, 2008 and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (Yin Fa [1996] No. 210) which was promulgated by the PBOC on June 20, 1996 and became effective on July 1, 1996. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is generally freely convertible for payments of current account items,

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such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of SAFE or its local counterparts is obtained.

According to the Announcement on Improving the Reform of the Renminbi (《關於完善人民幣匯率形成機制改革的公告》) issued by the PBOC on July 21, 2005, the PRC began to implement a regulated and managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand with reference to a basket of currencies. The Renminbi exchange rate is no longer pegged to the US dollar. The PBOC will publish the closing price of a foreign currency such as the US dollar traded against the Renminbi in the interbank foreign exchange market on each trading day after the closing of the market, and will fix the central parity for the transaction of such foreign currency against Renminbi on the following trading day.

From January 4, 2006, the PBOC introduced over-the-counter transactions into the inter-bank spot foreign exchange market for the purpose of improving the formation mechanism of the central parity of RMB exchange rates, and the practice of matching was kept at the same time. In addition, the liquidity of the foreign exchange market was also improved by adopting a market-making system in the interbank foreign exchange market.

The Foreign Exchange Control Regulations, which became effective on August 5, 2008, have made substantial changes to the foreign exchange regulatory system of the PRC. First, the Foreign Exchange Control Regulations adopted an approach of balancing the inflow and outflow of foreign exchange fund. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administration authorities. Second, the Foreign Exchange Control Regulations improved the mechanism for determining the Renminbi exchange rate based on market supply and demand. Third, the Foreign Exchange Control Regulations enhanced the monitoring of cross-border foreign exchange fund flows. In the event that international revenues and expenditure suffer or may suffer a material misbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard or control measures on international revenues and expenditure. Fourth, the Foreign Exchange Control Regulations enhanced the supervision and administration of foreign exchange transactions and grant extensive authority to the SAFE to strengthen its supervisory and administrative ability.

According to the relevant State rules and regulations, all of the foreign exchange revenue of the PRC enterprises from the current account transactions may be retained or sold to financial institutions operating a foreign exchange sale or settlement business. Foreign exchange income from loans granted by overseas entities or from the issuance of bonds and shares is not required to be sold to, but may be deposited in foreign exchange accounts at, designated foreign exchange banks.

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PRC enterprises (including foreign investment enterprises) which need foreign exchange for transactions relating to current account items may, without the approval of the SAFE, effect payment from their foreign exchange accounts or at the designated foreign exchange banks, on the strength of valid receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange may, on the strength of resolutions of the board of directors or the shareholders' meeting approving the distribution of profits, effect payment from their foreign exchange accounts or convert and pay dividends at the designated foreign exchange banks.

The Decision of the State Council on Cancelling and Adjusting a Group of Administrative Approval Items and Other Matters (《國務院關於取消和調整一批行政審批項目等事項的決定》) (Guo Fa [2014] No. 50), which was issued and became effective on October 23, 2014, has cancelled the approval by the SAFE and its branches for matters concerning the repatriation and settlement of foreign exchange of overseas-raised funds through overseas listing.

Pursuant to the Notice on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《關於境外上市外匯管理有關問題的通知》) (Hui Fa [2014] No. 54) issued by the SAFE on December 26, 2014, a domestic company shall, within 15 business days from completion of its initial public offering overseas, register the overseas listing with the SAFE's local branch at the place of its incorporation. The proceeds from an overseas listing of a domestic company may be remitted to a domestic account or deposited overseas, and the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

Pursuant to the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange of Capital Accounts (《關於改革和規範資本項目結匯管理政策的通知》) (Hui Fa [2016] No. 16) issued by the SAFE on June 9, 2016, discretionary settlement of foreign exchange income in capital account can be settled at the banks based on the actual operating needs of the domestic institutions. The proportion of discretionary settlement of foreign exchange capital income for domestic institutions is temporarily set at 100%. The SAFE may timely adjust the above proportion based on international revenue and expenditure situations.

APPENDIX IV

SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The PRC legal system

The PRC legal system is based on the PRC Constitution (《中華人民共和國憲法》) which was revised and took effect on March 11, 2018 (hereinafter referred to as the “**Constitution**”) and is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is the signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (《中華人民共和國立法法》) which was revised and took effect on March 15, 2015 (hereinafter referred to as the “**Legislation Law**”), the NPC and its Standing Committee are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing State organs, civil, criminal and other matters. The Standing Committee of the NPC formulates and amends the laws other than those required to be enacted by the NPC and to supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws. The people’s congresses of the provinces, autonomous regions and municipalities and their standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical and cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the people’s congresses of the relevant provinces or autonomous regions. The standing committees of the people’s congresses of the provinces or autonomous regions shall examine the legality of local regulations submitted for approval, and such approval shall be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of the relevant provinces or autonomous regions. Where, during the examination for approval of local regulations of cities divided into districts by the standing committees of the people’s congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people’s governments of

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the provinces or autonomous regions, a decision should be made to resolve the issue. People's congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the ethnic groups in the areas concerned.

The ministries and commissions of the State Council, PBOC, the National Audit Office and the subordinate institutions with administrative functions directly under the State Council may formulate departmental rules and regulations within the permissions of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, in cases where the scope of provisions of laws or decrees needs to be further defined or additional stipulations need to be made, the Standing Committee of the NPC shall provide interpretations or make stipulations by means of decrees. Issues related to the application of laws in a court trial should be interpreted by the Supreme People's Court, issues related to the application of laws in a prosecution process of the procuratorate shall be interpreted by the Supreme People's Procuratorate, and issues related to laws other than the abovementioned shall be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional regulations is vested in the regional legislative and administrative authorities which promulgate such regulations.

The PRC judicial system

Under the Constitution, the Law of Organization of the People's Court of the PRC (2018 Revision) (《中華人民共和國人民法院組織法(2018修訂)》) and the Law of Organization of the People's Procuratorate of the PRC (2018 Revision) (《中華人民共和國人民檢察院組織法(2018修訂)》), the people's courts of the PRC are divided into the Supreme People's Court, the local people's courts at all levels and special people's courts. The local people's courts at all levels are divided into three levels, namely, the basic people's courts, the intermediate people's courts and the higher people's courts. The basic people's courts may set up certain civil courts based on the status of the region, population and cases. The Supreme People's Court shall be the highest judicial organ of the State. The Supreme People's Court shall supervise the administration of justice by the local people's courts at all levels and by the special people's courts. The people's courts at a higher level shall supervise the judicial work of the people's courts at lower levels. The people's procuratorates of the PRC are divided into the Supreme People's Procuratorate, the local people's procuratorates at all levels, Military Procuratorates

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and other special people’s procuratorates. The Supreme People’s Procuratorate shall be the highest procuratorial organ. The Supreme People’s Procuratorate shall direct the work of the local people’s procuratorates at all levels and of the special people’s procuratorates; the people’s procuratorates at higher levels shall direct the work of those at lower levels.

The people’s courts employ a two-tier appellate system, i.e., judgments or rulings of the second instance at the people’s courts are final. A party may appeal against the judgment or ruling of the first instance of a local people’s courts. The people’s procuratorate may present a protest to the people’s courts at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within the stipulated period, the judgments or rulings of the people’s courts are final. Judgments or rulings of the second instance of the intermediate people’s courts, the higher people’s courts and the Supreme People’s Court and those of the first instance of the Supreme People’s Court are final. However, if the Supreme People’s Court or the people’s courts at the next higher level finds any definite errors in a legally effective final judgment or ruling of the people’s court at a lower level, the case can be retried according to judicial supervision procedures.

The Civil Procedure Law of the PRC (《中華人民共和國民事訴訟法》) (hereinafter referred to as the “**PRC Civil Procedure Law**”) adopted on April 9, 1991 and latest amended on December 24, 2021, prescribes the conditions for instituting a civil action, the jurisdiction of the people’s court, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC shall abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant’s place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people’s court having jurisdiction should be located at places directly connected with the disputes, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. Meanwhile, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

A foreign individual, a stateless person, a foreign enterprise or a foreign organization is given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a people’s court. Should a foreign court limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens or enterprises of such foreign country. A foreign individual, a stateless person, a foreign enterprise or a foreign organization shall engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a people’s court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people’s court and a foreign court may request each other to serve documents, conduct investigation and collect evidence and conduct other actions on its behalf. A people’s court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

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All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people’s court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people’s court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment against such party.

Where a party requests for enforcement of a legally effective judgment or ruling made by a people’s court, but the opposite party or his property is not within the territory of the People’s Republic of China, the party may directly apply to the foreign court with jurisdiction for recognition and enforcement of the judgment or ruling, or the people’s court may, in accordance with the provisions of international treaties to which the PRC is a signatory or in which the PRC is a participant or according to the principle of reciprocity, request for recognition and enforcement by the foreign court. Similarly, for a legally effective judgment or ruling made by a foreign court that requires recognition and enforcement by a people’s court of the PRC, a party may directly apply to an intermediate people’s court of the PRC with jurisdiction for recognition and enforcement of the judgment or ruling, or the foreign court may, in accordance with the provisions of international treaties to which its country and the PRC are signatories or in which its country is a participant or according to the principle of reciprocity, request for recognition and enforcement by the people’s court, unless the people’s court considers that the recognition or enforcement of such judgment or ruling would violate the basic legal principles of the PRC, its sovereignty or national security or would not be in social and public interest.

The Company Law of the PRC

The PRC Company Law was adopted by the Standing Committee of the Eighth NPC at its Fifth Session on December 29, 1993 and came into effect on July 1, 1994. It was successively amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. The newly revised PRC Company Law has been implemented since October 26, 2018.

Set out below is a summary of the major provisions of the PRC Company Law.

General

A “joint stock limited company” refers to a corporate legal entity incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties. The liability of the company for its own debts is limited to the total amount of all assets it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

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Incorporation

A company may be established by promotion or subscription. A company shall have a minimum of two but no more than 200 people as its promoters, over half of which shall have a domicile within the PRC. Companies established by promotion are companies of which the registered capital is the total share capital subscribed for by all the promoters registered with the company's registration authorities. No share offering shall be made before the shares subscribed for by promoters are fully paid up. For companies established by share offering, the registered capital is the total paid-up share capital as registered with the company's registration authorities. If laws, administrative regulations and State Council decisions provide otherwise on paid-in registered capital and the minimum registered capital, a company should follow such provisions.

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters' agreements. After the promoters have confirmed the capital contribution under the articles of association, a board of directors and a supervisory board shall be elected and the board of directors shall apply for registration of establishment by filing the articles of association with the company registration authorities, and other documents as required by the law or administrative regulations.

Where companies are incorporated by subscription, not less than 35% of their total number of shares shall be subscribed for by the promoters, unless otherwise provided by laws or administrative regulations. A promoter who offers shares to the public shall publish a document and prepare a subscription letter to be completed, signed and sealed by subscribers, specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC law, and underwriting agreements shall be entered into. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities in accordance with the agreement. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC laws shall be engaged to conduct a capital verification and furnish a certificate thereof. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription money. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued remain undersubscribed by the deadline stipulated in the document, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand

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that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days after the conclusion of the inauguration meeting, the board of directors shall apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after approval of registration has been given by the relevant company registration authority for industry and commerce and a business license has been issued.

A company's promoters shall be liable for: (1) the debts and expenses incurred in the establishment process jointly and severally if the company cannot be incorporated; (2) the subscription monies paid by the subscribers together with interest thereon at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and (3) the compensation of any damages suffered by the company in the course of its establishment as a result of the promoters' fault.

Share capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed shall be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation.

The issuance of shares shall be conducted in a fair and equitable manner. Each share of the same class shall rank *pari passu*. Shares of the same class issued at the same time shall be issued on the same conditions and at the same price. The same price per share shall be paid by any share subscriber (whether an entity or an individual). The share offering price may be equal to or greater than the nominal value of the share, but may not be less than the nominal value.

Under the PRC Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters: (1) the name and domicile of each shareholder; (2) the number of shares held by each shareholder; (3) the serial numbers of shares held by each shareholder; and (4) the date on which each shareholder acquired the shares.

Increase in share capital

Pursuant to the relevant provisions of the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at a general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

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Reduction of share capital

A company shall reduce its registered capital in accordance with the following procedures prescribed by the PRC Company Law: (1) the company shall prepare a balance sheet and a property list; (2) the reduction of registered capital shall be approved by shareholders at a general meeting; (3) the company shall notify its creditors within 10 days and publish an announcement in newspapers within 30 days from the day on which the resolution approving the reduction was passed; (4) the creditors of the company are entitled to require the company to repay its debts or provide guarantees for such debts within 30 days from receipt of the notification or within 45 days from the date of the announcement if he/she/it has not received any notification; and (5) the company shall apply to the company registration authority for change in registration.

Repurchase of shares

Pursuant to the PRC Company Law, a company may not repurchase its own shares other than for the following purposes: (1) reducing its registered capital; (2) merging with other companies which hold its shares; (3) carrying out an employee stock ownership plan or equity incentive plan; (4) acquiring its shares at the request of its shareholders who vote in a shareholders' general meeting against a resolution regarding a merger and division; (5) utilizing the shares for conversion of listed corporate bonds which are convertible into shares; and (6) where it is necessary for the listed company to safeguard the value of the company and the interests of its shareholders. The acquisition by a company of its own shares on the grounds set out in item (1) to (2) above shall be approved by way of a resolution of a shareholders' general meeting; the acquisition by a company of its own shares in circumstances as set out in items (3), (5) and (6) above may be approved by way of a resolution at a board meeting with two-third or more of the directors present in accordance with the provisions of the company's articles of association or the authorization of the shareholders' general meeting.

Following the acquisition by a company of its own shares in accordance with these requirements, such shares shall be canceled within 10 days from the date of the acquisition under the circumstance in item (1); such shares shall be transferred or canceled within six months under the circumstances in items (2) or (4); the total shares held by the Company shall not exceed 10% of the total shares issued by the Company and such shares shall be transferred or canceled within three years under the circumstances in items (3), (5) or (6).

A listed company shall perform its information disclosure obligations in accordance with the provisions of the PRC Securities Law when acquiring its own shares. The acquisition by a listed company of its own shares in circumstances as set out in items (3), (5) and (6) of this article shall be conducted through open centralized trading.

The Company shall not accept the shares of the Company as the subject of pledge.

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Transfer of shares

Shares held by shareholders may be transferred legally. Pursuant to the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in other manner specified by laws and administrative regulations. Following the transfer, the company shall enter the names and addresses of the transferees into its share register. No changes of registration in the share register described above shall be effected during a period of 20 days prior to convening a shareholders' general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, unless otherwise stipulated by laws on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder.

Pursuant to the PRC Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public offering of shares may not be transferred within one year of the date of the company's listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and changes in such shareholdings. During their terms of office, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year from the date of the company's listing on a stock exchange, nor within six months after they leave office in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

Shareholders

Under the PRC Company Law, the rights of shareholders include the rights: (1) to receive a return on assets, participate in significant decision-making and select management personnel; (2) to petition the people's court to revoke any resolution passed on a shareholders' general meeting or a meeting of the board of directors that has been convened or whose voting has been conducted in violation of the laws, administrative regulations or the articles of association, or any resolution the contents of which is in violation of the articles of association, provided that such petition shall be submitted within 60 days of the passing of such resolution; (3) to transfer the shares of the shareholders legally; (4) to attend or appoint a proxy to attend shareholders' general meetings and exercise the voting rights; (5) to inspect the articles of association, share register, counterfoil of company debentures, minutes of shareholders' general meetings, board resolutions, resolutions of the board of supervisors and financial and accounting reports, and to make suggestions or inquiries in respect of the company's operations; (6) to receive dividends in respect of the number of shares held; (7) to participate in distribution of residual properties of the company in proportion to their shareholdings upon the liquidation of the company; and (8) any other shareholders' rights provided for in laws, administrative regulations, other normative documents and the articles of association.

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The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of subscription monies agreed to be paid in respect of the shares taken up by them and any other shareholder obligation specified in the articles of association.

Shareholders' general meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The general meeting may exercise its powers: (1) to decide on the company's operational objectives and investment plans; (2) to elect and dismiss the directors and supervisors not being representative(s) of employees and to decide on the matters relating to the remuneration of directors and supervisors; (3) to review and approve the reports of the board of directors; (4) to review and approve the reports of the board of supervisors or the reports of the supervisors; (5) to review and approve the company's annual financial budgets proposals and final accounts proposals; (6) to review and approve the company's profit distribution proposals and loss recovery proposals; (7) to decide on any increase or reduction of the company's registered capital; (8) to decide on the issue of corporate bonds; (9) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form; (10) to amend the company's articles of association; and (11) to exercise any other authority stipulated in the articles of association.

Pursuant to the PRC Company Law, a shareholders' general meeting is required to be held once every year within six months after the end of the previous accounting year. An extraordinary general meeting is required to be held within two months upon the occurrence of any of the following: (1) the number of directors is less than the number required by law or less than two-thirds of the number specified in the articles of association; (2) the total outstanding losses of the company amounted to one-third of the company's total paid-in share capital; (3) shareholders individually or in aggregate holding 10% or more of the company's shares request to convene an extraordinary general meeting; (4) the board deems necessary; (5) the board of supervisors so proposes; or (6) any other circumstances as provided for in the articles of association.

A shareholders' general meeting shall be convened by the board of directors and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or is not performing his duties, a director recommended by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties, the board of supervisors shall convene and preside over the shareholders' general meeting in a timely manner. If the board of supervisors fails to convene and preside over the shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over the shareholders' general meeting.

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In accordance with the PRC Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days prior to the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. For the issuance of bearer share certificates, the time and venue of and matters to be considered at the meeting shall be announced 30 days prior to the meeting. Shareholders individually or jointly holding more than three percent of the shares of the company may submit an interim proposal in writing to the board of directors within 10 days before the general meeting. The board of directors shall notify other shareholders within two days upon receipt of the proposal, and submit the interim proposal to the general meeting for deliberation. The contents of the interim proposal shall fall within the scope of powers of the general meeting, and the proposal shall provide clear agenda and specific matters for a resolution is to be made. A general meeting shall not make any resolution in respect of any matter not set out in the notices. Holders of bearer share certificates who intend to attend a general meeting shall deposit their share certificates with the company during the time from five days before the meeting to the conclusion of the meeting.

Pursuant to the Official Reply of the State Council Regarding Adjusting the Application of Provisions to Matters Including the Notice Period for Convention of Shareholders’ Meetings by Overseas Listed Companies (《國務院關於調整適用在境外上市公司召開股東大會通知期限等事項規定的批覆》(Guo Han [2019] No. 97)), which came into effect on October 17, 2019, for those joint stock limited companies registered in the PRC but listed overseas, the requirements for the notice period for convening a shareholders’ general meeting, shareholders’ proposal right, and the procedures for convening a shareholders’ general meeting shall be collectively governed by the relevant provisions of the PRC Company Law

Pursuant to the PRC Company Law, shareholders present at a shareholders’ general meeting have one vote for each share they hold, save that the Company’s shares held by the company are not entitled to any voting rights.

An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Pursuant to the PRC Company Law, resolutions of the general meeting shall be passed by more than half of the voting rights held by shareholders present at the meeting, with the exception of resolutions relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, in each case of which shall be passed by more than two-thirds of the voting rights held by the shareholders present at the meeting. Where the PRC Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company and such other matters shall be approved by

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way of resolution of the general meeting, the board of directors shall convene a shareholders' general meeting promptly to vote on such matters. A shareholder may entrust a proxy to attend the general meeting on his/her behalf. The proxy shall present the shareholders' power of attorney to the company and exercise voting rights within the scope of authorization.

Minutes shall be prepared in respect of matters considered at the general meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Board of directors

A company shall have a board of directors, which shall consist of 5 to 19 members. Members of the board of directors may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly re-elected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of director results in the number of directors being less than the quorum.

Under the PRC Company Law, the board of directors may exercise its powers:

- (1) to convene shareholders' general meetings and report on its work to the shareholders' general meetings;
- (2) to implement the resolutions passed by the shareholders at the shareholders' general meetings;
- (3) to decide on the company's operational plans and investment proposals;
- (4) to formulate proposal for the company's annual financial budgets and final accounts;
- (5) to formulate the company's profit distribution proposals and loss recovery proposals;
- (6) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;
- (7) to formulate proposals for the merger, division or dissolution of the company or change of corporate form;
- (8) to decide on the setup of the company's internal management organs;

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- (9) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations;
- (10) to formulate the company's basic management system; and
- (11) to exercise any other authority stipulated in the articles of association.

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. An extraordinary meeting of the board of directors may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the supervisory board. The chairman shall convene the meeting within 10 days of receiving such proposal and preside over the meeting. The board of directors may otherwise determine the means and the period of notice for convening an extraordinary meeting of the board of directors. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization. Meanwhile, the board of directors shall keep minutes of resolutions passed at board meetings. The minutes shall be signed by the directors present at the meeting.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company: (1) a person who is unable or has limited ability to undertake any civil liabilities; (2) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist economic order, or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence; (3) a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise; (4) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; and (5) a person who is liable for a relatively large amount of debts that are overdue.

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Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the company.

Under the PRC Company Law, the board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing, or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing, or is not performing his/her duties, a director jointly elected by more than half of the directors shall perform his/her duties.

Supervisory board

A company shall have a supervisory board composed of not less than three members. The supervisory board shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company's staff, among which the proportion of representatives of the company's staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company's staff at the supervisory board shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. The supervisory board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the supervisory board shall be elected by more than half of all the supervisors. Directors and senior management members shall not act concurrently as supervisors.

According to the Reply of the Overseas Listing Department of CSRC and the Production System Department of the State Commission for Restructuring the Economic System on Opinions Concerning the Supplement and Amendment to Articles of Association by Companies to Be Listed in Hong Kong (《中國證監會海外上市部、國家體改委生產體制司關於到香港上市公司對公司章程作補充修改的意見的函》), the chairman of the supervisory board shall be selected by more than two-thirds of all the supervisors.

The chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the chairman of the supervisory board is incapable of performing, or is not performing his/her duties, the vice chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the vice chairman of the supervisory board is incapable of performing, or is not performing his/her duties, a supervisor elected by more than half of the supervisors shall convene and preside over supervisory board meetings.

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Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisor results in the number of supervisors being less than the quorum.

The supervisory board may exercise its powers:

- (1) to review the company's financial position;
- (2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or resolutions of the shareholders' general meetings;
- (3) when the acts of a director or a senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts;
- (4) to propose the convening of extraordinary shareholders' general meetings and to convene and preside over shareholders' general meetings when the board fails to perform the duty of convening and presiding over shareholders' general meetings under the PRC Company Law;
- (5) to submit proposals to the shareholders' general meetings;
- (6) to bring actions against directors and senior management personnel pursuant to the relevant provisions of the PRC Company Law; and
- (7) to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The supervisory board may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

Manager and senior management

Under the relevant requirements of the PRC Company Law, a company shall have a manager who shall be appointed or removed by the board of directors.

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Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director.

According to the PRC Company Law, senior management refers to manager, deputy manager, financial officer, secretary to the board of a listed company and other personnel as stipulated in the articles of association.

Duties of directors, supervisors, general managers and other senior management

Directors, supervisors and senior management are required under the PRC Company Law to comply with the relevant laws, administrative regulations and the articles of association, and shall be obliged to be faithful and diligent towards the Company. Directors, supervisors and management personnel are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property. Furthermore, directors and senior management are prohibited from:

- (1) misappropriating company funds;
- (2) depositing company funds into accounts under their own names or the names of other individuals;
- (3) loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors;
- (4) entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting;
- (5) using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting;
- (6) accepting for their own benefit commissions from a third party for transactions conducted with the company;
- (7) unauthorized divulgence of confidential information of the company; and
- (8) other acts in violation of their duty of loyalty to the company.

Income generated by directors or senior management in violation of this Article shall be of the benefit of the Company.

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A director, supervisor or senior management who contravenes law, administrative regulation or the articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. Directors and senior management shall furnish all true information and data to the supervisory board, without impeding the discharge of duties by the supervisory board or supervisors.

Where a director or senior management contravenes laws, administrative regulations or the articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate more than 1% of the company's shares consecutively for more than 180 days may request in writing that the supervisory board institute litigation at the people's court. Where the supervisory board violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at the people's court on its behalf. If the supervisory board or the board of directors refuses to institute litigation after receiving this written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at the people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at the people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at the people's court.

Finance and accounting

Under the PRC Company Law, A company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments under the State Council. At the end of each accounting year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with laws. The financial and accounting reports shall be prepared in accordance with laws, administrative regulations and the regulations of the financial departments under the State Council. The company's financial and accounting reports shall be made available for shareholders' inspection at the company within 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings shall announce its financial and accounting reports.

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When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached more than 50% of the PRC company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of its own shares held by it.

The premium over the nominal value per share of the company on issue and other income as required by relevant governmental department to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

Appointment and dismissal of auditors

Pursuant to the PRC Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of data.

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Profit distribution

According to the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided.

Amendments to the articles of association

Pursuant to PRC Company Law, the resolution of a shareholders' general meeting regarding any amendment to a company's articles of association requires affirmative votes by more than two-thirds of the votes held by shareholders attending the meeting.

Dissolution and liquidation

Under the PRC Company Law, a company shall be dissolved for any of the following reasons:

- (1) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;
- (2) the shareholders have resolved at a shareholders' general meeting to dissolve the company;
- (3) the company shall be dissolved by reason of its merger or division;
- (4) the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or
- (5) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders' interests.

In the event of paragraph (1) above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph (1), (2), (4) or (5) above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' general meeting. If a liquidation committee is not established within the stipulated period, the company's creditors can apply to the people's court for setting up a liquidation committee with designated relevant personnel to conduct the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

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The liquidation committee may exercise following powers during the liquidation:

- (1) to sort out the company's assets and to prepare a balance sheet and an inventory of assets;
- (2) to notify the company's creditors or publish announcements;
- (3) to deal with any outstanding business related to the liquidation;
- (4) to pay any overdue tax together with any tax arising during the liquidation process;
- (5) to settle the company's claims and liabilities;
- (6) to handle the company's remaining assets after its debts have been paid off; and
- (7) to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within 10 days of its establishment, and publish an announcement in newspapers within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification.

A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.

Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people's court, the liquidation committee shall hand over the administration of the liquidation to the people's court.

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Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' general meeting or the people's court for verification, and to the company registration authority for the cancellation of company registration, and an announcement of its termination shall be published. Members of the liquidation committee shall be faithful in the discharge of their duties and shall perform their liquidation duties in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. Members of the liquidation committee who have caused the company or its creditors to suffer from any loss due to intentional fault or gross negligence, should be liable for making compensations to the company or its creditors. In addition, liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

Overseas listing

The shares of a company shall only be listed overseas after filed with the CSRC, and the listing must be arranged in accordance with procedures specified by the State Council.

Loss of share certificates

A shareholder may, in accordance with the public notice procedures set out in the PRC Civil Procedure Law, apply to a people's court if his share certificate(s) in registered form is either stolen, lost or destroyed, for a declaration that such certificate(s) will no longer be valid. After the people's court declares that such certificate(s) will no longer be valid, the shareholder may apply to the company for the issue of a replacement certificate(s).

Merger and division

Under the PRC Company Law, a merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in newspapers within 30 days. A creditor may, within 30 days from the date of reception of the notification, or within 45 days from the date of the announcement if he has not received such notification, request the company to settle any outstanding debts or provide corresponding guarantees.

In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company. In case of a division, the company's assets shall be divided and a balance sheet and an inventory of assets shall be prepared. The companies shall within 10 days of the date of passing the resolution approving the division notify their respective creditors and publicly announce the division in newspapers within 30 days.

Unless an agreement in writing is reached with creditors before the company's division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

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Changes in the registration as a result of the merger or division shall be registered with the relevant administration authority of the company in accordance with the law.

The PRC Securities Laws, Regulations and Regulatory Regimes

The PRC has promulgated a series of regulations that relate to the issue and trading of the Shares and disclosure of information. In October 1992, the State Council established the Securities Committee and CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering CSRC. CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and CSRC and reformed CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) govern the application and approval procedures for public offerings of shares, issuing of and trading of shares, the acquisition of listed companies, deposit, clearing and transfer of shares, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

On December 25, 1995, the State Council promulgated the Special Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的特別規定》), which were repealed on March 31, 2023. These regulations principally governed the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The PRC Securities Law (《中華人民共和國證券法》) (the “**Securities Law**”) took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised Securities Law was implemented on March 1, 2020. It was the first national securities law in the PRC, comprehensively regulating activities in the PRC securities market, and is divided into 14 chapters and 226 articles, including the issue and trading of securities, takeovers by listed companies and the duties and responsibilities of the securities exchanges, securities companies, securities clearing institutions and securities regulatory authorities. Article 224 of the Securities Law provides that domestic enterprises shall satisfy the relevant requirements of the State Council when it issues securities or lists securities outside the PRC directly or indirectly. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and CSRC.

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Arbitration and enforcement of arbitral awards

The Arbitration Law of the PRC (2017 Amendment) (《中華人民共和國仲裁法(2017修正)》) (the “**PRC Arbitration Law**”) was enacted by the Standing Committee of the NPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. It is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration provisions in accordance with the PRC Arbitration Law and the PRC Civil Procedure Law. Where the involved parties have agreed to settle disputes by means of arbitration, a people’s court will refuse to handle a legal proceeding initiated by one of the parties at such people’s court, unless the arbitration agreement has lapsed.

Under the PRC Arbitration Law and PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If one party fails to comply with the arbitral award, the other party to the award may apply to a people’s court for its enforcement. However, the people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including but not limited to irregularity in the composition of the arbitration tribunal, or the making of an award on matters beyond the scope of the arbitration agreement or outside the jurisdiction of the arbitration commission).

Any party seeking to enforce an award of a foreign affairs arbitration organ of the PRC against a party who or whose property is not located within the PRC may apply to a foreign court with jurisdiction over the relevant matters for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitral body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (《承認及執行外國仲裁裁決公約》) (the “**New York Convention**”) passed on June 10, 1958 pursuant to a resolution passed by the Standing Committee of the NPC on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse recognition and enforcement under certain circumstances, including where the recognition or enforcement of the arbitral award is against the public policy of that state. At the time of the PRC’s accession to the Convention, the Standing Committee of the NPC declared that (1) the PRC will only apply the New York Convention to the recognition and enforcement of arbitral awards made in the territories of other parties based on the principle of reciprocity; and (2) the New York Convention will only apply to disputes deemed under PRC laws to be arising from contractual or non-contractual mercantile legal relations.

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An arrangement for mutual enforcement of arbitral awards between Hong Kong and the Supreme People’s Court of China was reached. The Supreme People’s Court of China adopted the Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《關於內地與香港特別行政區相互執行仲裁裁決的安排》) on June 18, 1999, which went into effect on February 1, 2000, which was amended by the Supplemental Arrangement of the Supreme People’s Court for the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region implemented in November 27, 2020 and the Supplemental Arrangement of the Supreme People’s Court for the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (2021) (《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(2021年)》) implemented in May 19, 2021. The arrangements reflects the spirit of the New York Convention. Under the arrangements, the awards by the Mainland arbitral bodies recognized by Hong Kong may be enforced in Hong Kong and the awards by the Hong Kong arbitral bodies may also be enforced in the Mainland China. If the Mainland court finds that the enforcement of awards made by the Hong Kong arbitral bodies in the Mainland will be against public interests of the Mainland, the awards may not be enforced.

SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND PRC COMPANY LAW

The Hong Kong laws applicable to a company incorporated in Hong Kong are the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance and are supplemented by common law and the rules of equity that are applicable to Hong Kong. As a joint stock limited company established in the PRC that is seeking a listing of shares on the Stock Exchange, the Company is governed by the PRC Company Law and all other rules and regulations promulgated pursuant to the PRC Company Law.

Set out below is a summary of certain material differences between Hong Kong laws applicable to a company incorporated in Hong Kong and the PRC Company Law applicable to a joint stock limited company incorporated under the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.

Incorporation of company

Under Hong Kong laws, a company with share capital, shall be incorporated by the Registrar of Companies in Hong Kong and the company will acquire an independent corporate existence upon its incorporation. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain provisions that restrict a member’s right to transfer shares. A public company’s articles of association do not contain such provisions.

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or subscription. The amended PRC Company Law which came into effect on October 26, 2018 has no provision on the maximum registered capital of joint stock companies, except that laws, administrative regulations and State Council decisions have separate provisions on paid-in registered capital and the minimum registered capital of joint stock companies, in which case the company should follow such provisions.

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Share capital

The Companies Ordinance does not provide for authorized share capital. The share capital of a Hong Kong company would be its issued share capital. The full proceeds of a share issue will be credited to share capital and becomes a company's share capital. Under Hong Kong laws, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law provides that any increase in our registered capital must be approved by our shareholders' general meeting and the relevant PRC governmental and regulatory authorities. There are no minimum capital requirements for companies incorporated in Hong Kong.

Under the PRC Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and transfer procedures of property rights must be carried out to ensure no over-valuation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong laws.

Restrictions on shareholding and transfer of shares

Under PRC laws, our Domestic Shares, which are denominated and subscribed for in Renminbi, may only be subscribed for and traded by the government or government authorized departments, PRC legal persons, natural persons, qualified foreign institutional investors, or eligible foreign strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a foreign currency other than Renminbi, may only be subscribed for, and traded by investors from Hong Kong, Macau or Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors. However, qualified institutional investors and individual investors may trade Southbound Hong Kong trading Link and Northbound Shanghai trading Link (or the Northbound Shenzhen trading Link) shares via participating in Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

Under the PRC Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to the public offering cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited company held by its directors, supervisors and senior management transferred each year during their term of office shall not exceed 25% of the total shares they held in the company, and the shares they held in the company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after such person has left office. The articles of association may set other restrictive requirements on the transfer of the company's shares held by its directors, supervisors and senior management. There are no such restrictions on shareholdings and transfers of shares under Hong Kong laws apart from six-month lockup on the company's issue of shares and the 12-month lockup on controlling shareholders' disposal of shares.

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Financial assistance for acquisition of shares

The PRC Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company's shares.

Variation of class rights

The PRC Company Law has no special provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate separate regulations relating to other kinds of shares.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the approval of a special resolution of the holders of the relevant class at a separate general meeting; (ii) with the consent in writing of the holders representing at least 75% of the total voting rights of holders of the relevant class of shares or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

Directors, senior management and supervisors

The PRC Company Law, unlike the Companies Ordinance, does not contain any requirements relating to the declaration of directors' interests in material contracts, restrictions on companies providing certain benefits to directors and guarantees in respect of directors' liability and prohibitions against compensation for loss of office without shareholders' approval.

Board of supervisors

Under the PRC Company Law, a joint stock limited company's directors and the senior management are subject to the supervision of the board of supervisors. There is no mandatory requirement for the establishment of the board of supervisors for a company incorporated in Hong Kong.

Derivative action by minority shareholders

According to Hong Kong laws, as permitted by court, shareholders may initiate a derivative action on behalf of the company against directors who have any misconduct to the company if the directors control a majority of votes at a general meeting, thereby effectively preventing a company from suing the directors in breach of their duties in its own name.

The PRC Company Law provides shareholders of a joint stock limited company with the right so that in the event where the directors and senior management violate their obligations and cause damages to a company, the shareholders individually or jointly holding more than 1% of the shares in the company for more than 180 consecutive days may request in writing

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the board of supervisors to initiate proceedings in the people's court. In the event that the board of supervisors violates their obligations and cause damages to company, the above said shareholders may send written request to the board of directors to initiate proceedings in the people's court. Upon receipt of aforesaid written request from the shareholders, if the board of supervisors or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days from the date of receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company's interests, have the right to initiate proceedings directly to the people's court in their own name. limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors of the company in default.

Protection of minorities

Under Hong Kong laws, a shareholder who complains that the business of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to the court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong.

According to the PRC Company Law, in the event that the company encounters substantial difficulties in its operation and management and its continuance shall cause a significant loss to the interest of its shareholders, and where this cannot be resolved through other means, the shareholders who hold more than 10% of the total shareholders' voting rights of the company may present a petition to the People's Court for the dissolution of the company.

Notice of shareholders' general meetings

Under the PRC Company Law, notice of a shareholders' annual general meeting and an extraordinary shareholders meeting must be given to shareholders at least 20 days and 15 days before the meeting, respectively.

For a company incorporated in Hong Kong, the notice period for an annual general meeting is at least 21 days and in any other case, at least 14 days for a limited company and at least 7 days for an unlimited company.

APPENDIX IV

SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Quorum for shareholders' general meetings

Under the Companies Ordinance, the quorum for a general meeting must be at least two members unless the articles of association of the company otherwise provided. For companies with only one shareholder, the quorum must be one member. The PRC Company Law does not specify the quorum for a shareholders' general meeting.

Voting

Under the Companies Ordinance, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes casted by shareholders present in person, or by proxy, at a general meeting.

Under the PRC Company Law, the passing of any resolution requires more than one-half of the affirmative votes held by our shareholders present at a shareholders' meeting except in cases such as proposed amendments to our articles of association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require two-thirds of the affirmative votes cast by shareholders present at a shareholders' general meeting.

Financial disclosure

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders' annual general meeting. In addition, a joint stock limited company of which the shares are publicly issued must publish its financial report. The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors' report and directors' report, which are to be presented before the company's annual general meeting, not less than 21 days before such meeting. A joint stock limited company is required under the PRC laws to prepare its financial statements in accordance with the PRC GAAP.

Information on directors and shareholders

The PRC Company Law gives shareholders the right to inspect the company's articles of association, minutes of the shareholders' general meetings, share register, counterfoil of company debentures, resolutions of board meetings, resolutions of the board of supervisors meeting and financial and accounting reports, which is similar to the shareholders' rights of Hong Kong companies under Hong Kong laws.

Receiving agent

Under the PRC Company Law and Hong Kong laws, dividends once declared are debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under PRC laws, this limitation period is three years.

APPENDIX IV

SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Corporate reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its shareholders under Section 673 and Section 674 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders’ approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance.

Under PRC laws, merger, division, dissolution or change the form of a joint stock limited company has to be approved by shareholders in general meeting.

Dispute arbitration

In Hong Kong, disputes between shareholders on the one hand, and a company incorporated in Hong Kong or its directors on the other hand, may be resolved through legal proceedings in the courts.

Statutory reserve fund withdrawal

Under the PRC Company Law, when a joint stock limited company allocating the after-tax profits of the current year, a company shall allocate (10) ten percent of its profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong laws.

Remedies of the company

Under the PRC Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages. In addition, the Listing Rules require listed companies’ articles of association to provide for remedies of the company similar to those available under Hong Kong laws (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

APPENDIX IV

SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Dividends

A company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC laws on any dividends or other distributions payable to a shareholder. Under Hong Kong laws, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. A company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Fiduciary duties

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company's interests. Furthermore, the Companies Ordinance has codified the directors' statutory duty of care.

Under the PRC Company Law, directors, supervisors and senior management should be loyal and diligent.

Closure of register of members

The Companies Ordinance requires that the register of members of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days under certain circumstances) in a year, whereas, as required by the PRC Company Law, 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.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

This Appendix contains a summary of the principal provisions of the Articles of Association adopted by the Company on [●], 2023, which will become effective on the date on which the H Shares are [REDACTED] on the Hong Kong Stock Exchange. The main purpose of this Appendix is to provide potential [REDACTED] with an overview of the Articles of Association of the Company, and therefore it may not contain all the information that is important for potential [REDACTED].

SHARES AND REGISTERED CAPITAL

Shares of the Company shall take the form of share certificates. The shares issued by the Company shall be denominated in RMB. The par value per share is RMB1.00.

The Company shall issue shares in an open, fair and just manner, and each share of the same class shall have the same rights.

Shares of the same class issued at the same time shall be issued on the same conditions and at the same price. Any entity or individual shall pay the same price for each of the shares for which it or he or she subscribes for.

INCREASE, DECREASE AND REPURCHASE OF SHARES

Capital Increase

The Company may, based on its business and development needs and in accordance with the laws, regulations, the securities regulatory rules of the place where the Company’s shares are listed and the Articles of Association, increase its capital in the following ways, subject to separate resolutions of the shareholders’ general meeting:

1. public offering of shares;
2. non-public issuance of shares;
3. distributing bonus shares to its existing shareholders;
4. conversion of capital reserve into share capital;
5. other means as stipulated by laws and regulations, or as approved by securities regulatory rules of the place where the Company’s shares are [REDACTED] and the CSRC.

Capital Reduction

The Company may reduce its registered capital. When the Company needs to reduce its registered capital, it shall comply with the procedures stipulated in the Company Law, the Hong Kong Listing Rules and other relevant regulations and the Articles of Association.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

Shares Repurchase

The Company shall not buy back its shares, except in one of the following circumstances:

1. reducing the registered capital of the Company;
2. merging with another company that holds shares in the Company;
3. using shares for employee stock ownership plan or equity incentives;
4. shareholders who object to resolutions of the general meeting on merger or division of the Company requesting the Company to buy back their shares;
5. using the shares for conversion of corporate bonds issued by the Company which are convertible into shares;
6. where it is necessary for the Company to preserve its value and shareholders' interest.

The Company may repurchase its shares through public centralised trading or other methods recognised by laws, administrative regulations and the CSRC, and shall comply with applicable laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Company's shares are [REDACTED].

Where the Company repurchases its shares under the circumstances set out in items 1 and 2 above, a resolution shall be passed at the general meeting of the Company. Where the Company repurchases its shares under the circumstances set out in items 3, 5 and 6 above, a resolution may be passed at a Board meeting attended by more than two-thirds of the directors in accordance with the provisions of the Articles of Association or as authorised by the general meeting. Where the securities regulatory rules of the place where the shares of the Company are [REDACTED] provide otherwise, such provisions shall prevail, provided that such provisions are not in violation of the Company Law, the Securities Law, the Trial Administrative Measures and the Guidelines for the Articles of Association of Listed Companies.

Where the Company repurchases its shares under the circumstances set out in item 1 above, such shares shall be cancelled within 10 days from the date of repurchase; where the Company repurchases its shares under the circumstances set out in items 2 and 4, such shares shall be transferred or cancelled within six months; where the Company repurchases its shares under the circumstances set out in items 3, 5 and 6, the total number of shares held by the Company shall not exceed 10% of the total issued shares of the Company, and such shares shall be transferred or cancelled within three years.

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SUMMARY OF ARTICLES OF ASSOCIATION

Transfer of Shares

Shares of the Company held by the promoters shall not be transferred within one year from the date of establishment of the Company. Shares issued by the Company prior to the public offering of shares shall not be transferred within one year from the date on which the Company's shares are [REDACTED] and traded on the stock exchange(s).

Directors, Supervisors and senior management of the Company shall declare to the Company their holdings of shares (including preferred shares) in the Company and any changes thereof, and shall not transfer more than 25% of the total number of shares of same class of the Company held by them each year during their terms of office; the shares of the Company held by them shall not be transferred within one year from the date on which the shares of the Company are [REDACTED] and [REDACTED]. The above personnel shall not transfer the shares of the Company held by them within half a year after they leave the Company.

If the Company's shareholders holding 5% or above shares of the Company (excluding the recognized clearing houses or their agents as defined in the relevant ordinances in force under the laws of Hong Kong from time to time), Directors, Supervisors, senior management officers sell shares or other securities with an equity nature within six months after buying the same or buy shares or securities within six months after selling the same, the earnings arising therefrom shall belong to the Company and the Company's Board shall recover such earnings. However, the restriction shall not be applicable to any sale of shares by a securities company holding 5% or above of the Company's shares as a result of its purchase and underwriting of the untaken shares after offering and other circumstances stipulated by the CSRC.

The shares or other securities with an equity nature held by Directors, Supervisors, senior management officers and natural person shareholders referred to in the preceding paragraph include the shares or other securities with an equity nature held by their spouses, parents, children, and any of the above which is held by using others' accounts.

If the Company's Board does not comply with the provision of the first paragraph of this Article, the shareholders can request the Board to do so within 30 days. If the Company's Board does not enforce such right within the aforesaid period, the shareholders are entitled to commence litigations in the people's court in their own names for the interests of the Company.

If the Company's Board does not enforce the provision of the first paragraph of this Article, the responsible Directors shall bear joint and several liabilities in accordance with the laws.

REGISTER OF MEMBERS

The Company shall establish a register of members in accordance with the evidence provided by the securities registration authority and with reference to the laws, administrative regulations, departmental rules and the Hong Kong Listing Rules. The register of shareholders shall be sufficient evidence of the shareholders' shareholdings in the Company.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

The Company shall enter into a share custody agreement with the securities registration authority, regularly enquire the information of substantial shareholders and the changes in shareholdings (including pledge of equity interests) of substantial shareholders, and keep abreast of the shareholding structure of the Company. The original of register of holders of H Shares shall be maintained in Hong Kong and made available for inspection by shareholders. However, the Company may suspend registration of shareholders (if necessary) in accordance with applicable laws and regulations and the securities regulatory rules of the place where the Company's shares are [REDACTED].

When the Company convenes the general meeting, pays dividends, goes into liquidation or is involved in other actions that require the confirmation of shareholders' identity, the Board or the convenor of the general meeting shall fix a date as the equity registration date, upon expiration of which the shareholders whose names appear on the register of members shall be the shareholders entitled to relevant rights and interests.

RIGHTS AND OBLIGATIONS OF SHAREHOLDERS

Shareholders of the Company shall enjoy the following rights:

1. to receive dividends and other distributions in proportion to the number of shares held;
2. to request, summon, preside over, attend or appoint a proxy to attend shareholders' general meetings in accordance with the laws, and to exercise the corresponding voting rights (except where a shareholder is required by the securities regulatory rules of the place where the Company's shares are [REDACTED] to abstain from voting on a particular matter);
3. to supervise the operation of the Company, making suggestions or enquiries;
4. to transfer, give or pledge the shares held by them in accordance with the laws, administrative regulations and the Articles of Association;
5. to review the Articles of Association, the register of members (including the register of holders of H Shares), counterfoils of corporate bonds, minutes of general meetings, resolutions of the Board meetings, resolutions of the Board of Supervisors meetings and financial and accounting reports;
6. in the event of the termination or liquidation of the Company, to participate in the distribution of remaining assets of the Company in proportion to the number of shares held;
7. to request the Company to buy back the shares of shareholders objecting to resolutions of the general meeting concerning merger or division of the Company;

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SUMMARY OF ARTICLES OF ASSOCIATION

8. other rights stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Shareholders of the Company shall assume the following obligations:

1. to abide by laws, administrative regulations and the Articles of Association;
2. to pay subscription monies according to the number of shares subscribed and the method of subscription;
3. not to make divestment unless in the circumstances stipulated by laws and regulations;
4. not to abuse the rights of shareholders to damage the interests of the Company or that of other shareholders; not to abuse the independent status of the Company as a legal person and the limited liability of shareholders to damage the interests of the creditors of the Company;
5. other obligations imposed by laws, administrative regulations and the Articles of Association.

Shareholders of the Company who abuse their shareholders' rights and cause losses to the Company or other shareholders shall be liable for compensation in accordance with the law. Shareholders of the Company who abuse the independent status of the Company as a legal person and the limited liability of shareholders to evade debts and seriously damage the interests of the creditors of the Company shall bear joint and several liabilities for the debts of the Company.

RESTRICTIONS ON RIGHTS OF THE CONTROLLING SHAREHOLDERS

The controlling shareholders and de facto controllers of the Company shall not use their connected relations to damage the interests of the Company. If the violation causes losses to the Company, it shall be liable for compensation.

The controlling shareholders and de facto controllers of the Company shall have fiduciary duties towards the Company and its public shareholders. The controlling shareholder shall exercise its rights as a capital contributor in strict compliance with the laws. The controlling shareholder shall not damage the legitimate rights and interests of the Company and public shareholders by means of profit distribution, asset restructuring, external investment, fund appropriation, loan guarantee, etc., and shall not use its controlling status to damage the interests of the Company and public shareholders.

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SUMMARY OF ARTICLES OF ASSOCIATION

GENERAL MEETING

General Provisions of General Meetings

The shareholders' general meeting is the organ of authority of the Company and shall exercise the following functions and powers:

1. to decide on the Company's business policies and investment plans;
2. to elect and replace Directors and Supervisors who are not employee representatives and to decide on matters relating to the remuneration of Directors and Supervisors;
3. to consider and approve the reports of the Board;
4. To consider and approve the reports of the Board of Supervisors;
5. to consider and approve the annual financial budgets and final accounts of the Company;
6. to consider and approve the Company's profit distribution plans and loss recovery plans;
7. to resolve on the increase or reduction of the registered capital of the Company;
8. to resolve on the issue of corporate bonds;
9. to resolve on the merger, division, dissolution, liquidation or change of corporate form of the Company;
10. amendments to the Articles of Association;
11. to resolve on the appointment and dismissal of the accounting firm of the Company;
12. to consider and approve the guarantee matters stipulated in the Articles of Association;
13. to consider the purchase or disposal of material assets within one year with an amount exceeding 30% of the latest audited total assets of the Company;
14. to consider and approve the change in [REDACTED];
15. to consider share incentive schemes and employee share ownership schemes;

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16. to consider other matters required by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association to be decided by the general meeting.

The above-mentioned powers of general meeting shall not be exercised by the Board or other institutions or individuals by way of authorization. In addition to the above matters, the general meeting may authorise or entrust the Board and/or its authorised persons to handle the matters authorised or entrusted by it without violating the laws and regulations and the mandatory provisions of the relevant laws, regulations and regulatory rules of the place where the Company's shares are [REDACTED].

General meetings are divided into annual general meetings and extraordinary general meetings. The annual general meeting shall be convened once a year within six months after the end of the previous accounting year.

The Company shall convene an extraordinary general meeting within two months from the date of occurrence of any of the following circumstances:

1. 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;
2. when the unrecovered losses of the Company amount to one-third of the total amount of its paid-up share capital;
3. when shareholders individually or jointly holding 10% or more of the Company's shares so request;
4. when deemed necessary by the Board;
5. when proposed by the Board of Supervisors;
6. other circumstances stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Summoning of General Meetings

The independent non-executive Directors are entitled to propose to the Board to convene an extraordinary general meeting, and shall put forward its proposal to the Board in writing. For the proposal put forward by the independent non-executive Directors to request to convene an extraordinary general meeting, the Board shall, in accordance with the laws, the securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association, give a written reply on whether or not to convene the extraordinary general meeting within 10 days after receiving the proposal from the independent non-executive Directors.

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If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed. If the Board does not agree to convene the extraordinary general meeting, it shall explain the reasons in writing and make an announcement accordingly.

The Board of Supervisors shall have the right to propose to the Board to convene an extraordinary general meeting, and such proposal shall be made in writing. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association, give a written reply on whether to convene the extraordinary general meeting or not within 10 days after receipt of the proposal.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed. Any changes to the original proposal made in the notice shall be approved by the Board of Supervisors.

If the Board does not agree to convene the extraordinary general meeting or fails to give a reply within 10 days after receiving the proposal, the Board shall be deemed to be unable or fail to perform the duty of convening the general meeting, and the Board of Supervisors may summon and preside over the meeting on its own.

Shareholders individually or jointly holding 10% or more of the Company's shares shall have the right to request the Board of Directors in writing to convene an extraordinary general meeting. The Board shall, in accordance with the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the shares of the Company are [REDACTED] and the Articles of Association, give a written reply on whether to convene the extraordinary general meeting or not within 10 days after receipt of the proposal.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed. Any change to the original request made in the notice shall be subject to the consent of the relevant shareholders. If there are other provisions under laws, administrative regulations, departmental rules or securities regulatory rules of the place where the Company's shares are [REDACTED], such provisions shall prevail.

If the Board does not agree to convene an extraordinary general meeting or does not reply within 10 days upon receipt of the proposal, the shareholders individually or jointly holding more than 10% of the Company's shares shall have the right to propose to the Board of Supervisors to convene an extraordinary general meeting, and such proposal shall be made in writing.

If the Board of Supervisors agrees to convene the extraordinary general meeting, it shall issue a notice of general meeting within five days upon receipt of the request. Any changes to the original request in the notice shall be approved by the relevant shareholders.

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If the Board of Supervisors fails to issue the notice of the general meeting within the prescribed period, it shall be deemed that the Board of Supervisors will not convene and preside over the general meeting, and shareholders individually or jointly holding 10% or more of the Company's shares for more than 90 consecutive days may summon and preside over the meeting by themselves.

Proposals at General Meetings

When the Company convenes a general meeting, the Board, the Board of Supervisors and shareholders individually or jointly holding more than 3% of the Company's shares shall have the right to submit proposals to the Company.

Shareholders individually or jointly holding 3% or more of the Company's shares may submit provisional proposals in writing to the convener 10 days before a general meeting is convened. The convener shall issue a supplementary notice of the general meeting within two days upon receipt of the proposal to announce the contents of the provisional proposal, and shall submit it to the general meeting for consideration. The contents of the provisional proposal shall fall within the scope of power of the general meeting, and the subject issues for discussion and the specific matters to be resolved shall be clearly stated therein.

Except as provided in the preceding paragraph, the convener shall not amend the proposals set out in the notice of the general meeting or add any new proposals after issuing the notice of the general meeting.

Notice of General Meetings

The convener shall notify all shareholders by way of announcement 20 clear business days before the annual general meeting and shall notify all shareholders by way of announcement 10 clear business days or 15 days (whichever is longer) before the extraordinary general meeting.

Convening of General Meetings

All ordinary shareholders registered on the record date or their proxies are entitled to attend the general meeting. They shall exercise their voting rights in accordance with the relevant laws, regulations and the Articles of Association.

Individual shareholders who attend the meeting in person shall produce their identity cards or other effective document or proof of identity and stock account cards. Proxies of individual shareholders shall produce their valid identity cards and the power of attorney of the shareholder.

Shareholder that is a legal person may be represented at the meeting by its legal representative or a proxy appointed by it. If a legal representative attends the meeting, he/she should produce his/her identity card and valid proof that he/she is a legal representative; if a proxy attends the meeting, the proxy should produce his/her identity card and documents

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proving that he/she has been appointed by such legal person (unless a shareholder is a recognised clearing house as defined in the relevant ordinances in force from time to time under the laws of Hong Kong or the securities regulatory rules of the place where the shares of the Company are [REDACTED] or its nominee (hereinafter referred to as a "Recognised Clearing House"))).

If the shareholder is a Recognised Clearing House, the Recognised Clearing House may authorize one or more persons as it thinks fit to act as its representative (s) at any shareholders' general meeting or any creditors' meeting; however, if more than one person are so authorised, the power of attorney shall specify the number and class of shares in respect of which each such person is authorised, and the power of attorney shall be signed by the authorised person of the Recognised Clearing House. The person so authorised may attend the meeting on behalf of the Recognized Clearing House (without being required to present share certificate, notarized authorization and/or further evidence to prove that he/she is duly authorised) to exercise the rights as if he/she was an individual shareholder of the Company (and was entitled to the same legal rights as other shareholders, including the rights to speak and vote).

The proxy form shall contain a statement that whether in the absence of instructions from the shareholder the proxy may vote as he/she thinks fit.

If the proxy form is signed by a person authorised by the principal, the power of attorney or other authorization documents shall be notarized. The instrument appointing a proxy, the notarized power of attorney or other authorization documents shall be placed at the domicile of the Company or at such other place as specified in the notice convening the meeting.

If the principal is a legal person, its legal representative or such person as is authorised by resolution of its board of directors or other governing body to act as its representative may attend the general meeting of the Company.

Resolutions of General Meetings

Resolutions of the general meeting are divided into ordinary resolutions and special resolutions.

Ordinary resolutions shall be passed by votes representing more than half of the voting rights represented by the shareholders (including proxies) present at the meeting.

A special resolution shall be passed by votes representing more than two-thirds of the voting rights represented by the shareholders (including proxies) present at the meeting.

The following matters shall be approved by ordinary resolutions at a general meeting:

1. work reports of the Board and the Board of Supervisors;
2. profit distribution plans and loss recovery plans formulated by the Board;

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3. appointment and removal of members of the Board and the Board of Supervisors, their remuneration and method of payment;
4. annual budgets and final accounts of the Company;
5. annual reports of the Company;
6. the engagement and dismissal of accounting firms by the Company;
7. matters other than those required by the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are [REDACTED] or the Articles of Association to be approved by special resolution.

The following matters shall be approved by special resolutions at a general meeting:

1. increase or reduction of the registered capital, issuance of shares, warrants and other similar securities of any kind of the Company;
2. resolution on the issuance of corporate bonds or other securities and listing plans;
3. division, spin-off, merger, dissolution and liquidation or change of the form of the Company;
4. amendments to the Articles of Association;
5. purchase or disposal of material assets or provision of guarantee by the Company within 12 consecutive months with an amount exceeding 30% of the latest audited total assets of the Company;
6. share incentive scheme;
7. other matters stipulated by laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association, and other matters considered by the general meeting, by way of ordinary resolution, to have a material impact on the Company and need to be approved by special resolution.

DIRECTORS AND BOARD OF DIRECTORS

Directors

Directors shall be elected or replaced by the shareholders' general meeting, and may be removed by the shareholders' general meeting before the expiry of their terms of office. The term of office of the Directors shall be three years, and they may be re-elected and re-appointed.

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The term of office of the Directors shall commence from the date of their appointment until the expiry of the term of the current session of the Board. If the term of office of a director expires but re-election is not made responsively, the said director shall continue fulfilling the duties as director pursuant to laws, administrative regulations, departmental rules and the Articles of Association until a new director is elected.

The Board

The Company shall have a board of directors which shall be accountable to the general meeting. The Board shall consist of 11 Directors, including one chairman and does not include any vice chairman. The number of independent non-executive Directors shall not be less than three and shall represent more than one-third of the total number of Directors at any time.

The Board shall exercise the following powers:

1. to summon general meetings and report its work to the general meetings;
2. to implement the resolutions of the general meeting;
3. to decide on the Company's business plans and investment plans;
4. to formulate the Company's annual financial budgets and final accounts;
5. to formulate the Company's profit distribution plans and loss recovery plans;
6. to formulate proposals for the increase or reduction of the Company's registered capital, the issue of shares, bonds or other securities and listing plans;
7. to formulate plans for material acquisitions, purchase of shares of the Company or merger, division, dissolution and change of corporate form of the Company;
8. to decide on the Company's external investment, acquisition and disposal of assets, pledge of assets, external guarantees, entrusted financial management, connected transactions, external donations and other matters within the scope authorised by the general meeting;
9. to decide on the establishment of the Company's internal management structure and on the establishment or withdrawal of branches or representative offices of the Company;
10. to decide on the appointment or dismissal of the Company's general manager, secretary to the Board, and decide on their remuneration, rewards and punishments; to decide on the appointment or dismissal of the Company's deputy general manager, chief financial officer and other senior management based on the nomination of the general manager, and decide on their remuneration, rewards and punishments;

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11. to formulate the basic management system of the Company;
12. to formulate proposals for any amendment to the Articles of Association;
13. to manage the information disclosure of the Company;
14. to propose to the general meeting the appointment or replacement of the accounting firm that provides audit service of annual financial statements to the Company;
15. to listen to the work report of the general manager of the Company and inspect the work of the general manager;
16. to decide on the establishment of special committees of the Board and their composition;
17. to consider the acquisition of the Company's shares in accordance with the circumstances set forth in Article 24, Paragraph 1 (c), (e) and (f) of the Articles of Association;
18. other functions and powers conferred by laws, regulations, the listing rules of the stock exchange in the place where the Company's shares are [REDACTED], the general meeting or the Articles of Association.

Matters beyond the scope of authorization of the general meeting shall be submitted to the general meeting for consideration.

GENERAL MANAGER

The general manager shall be accountable to the Board and exercise the following powers:

1. to be in charge of the production, operation and management of the Company, organise the implementation of the resolutions of the Board and report to the Board;
2. to organise the implementation of the Company's annual business plan and investment plan;
3. to draft plans for the establishment of the Company's internal management structure;
4. to draft the basic management system of the Company;
5. to formulate the specific rules and regulations of the Company;
6. to propose to the Board to appoint or dismiss other senior management officers;

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7. to appoint or dismiss management personnel other than those required to be appointed or dismissed by the Board;
8. to exercise other powers conferred by the Articles of Association or the Board.

The general manager is to attend Board meetings.

SECRETARY TO THE BOARD

The Company shall have a secretary to the Board, who shall be responsible for the preparation of the general meetings and Board meetings of the Company, keeping of documents, management of shareholders' information of the Company and handling matters such as information disclosure.

The secretary to the Board shall comply with the relevant provisions of laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association.

BOARD OF SUPERVISORS

The Company shall have a Board of Supervisors. The Board of Supervisors shall consist of six Supervisors, including three shareholders' representatives and three staff representatives.

The Board of Supervisors shall have one chairman, and may have vice chairmen. The employee representatives of the Board of Supervisors shall be democratically elected by the Company's employees at the employee representative assembly, employee meeting or otherwise.

The Board of Supervisors shall exercise the following powers in accordance with laws:

1. it shall review the regular reports of the Company prepared by the Board and to provide written review opinions;
2. to examine the financial affairs of the Company;
3. to supervise the performance of duties by Directors and senior management in violation of laws, administrative regulations, the securities regulatory rules of the place where the Company's [REDACTED] are [REDACTED] or the Articles of Association and to propose the removal of Directors and senior management who have violated laws, administrative regulations, the Articles of Association or the resolutions of the shareholders' general meetings;
4. to demand rectification from a Director, general manager or other senior management when the acts of such persons are detrimental to the interests of the Company;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

5. to propose the convening of extraordinary general meetings and to summon and preside over general meetings when the Board fails to perform the duty of summoning and presiding over general meetings under the Company Law;
6. to submit proposals to the general meeting;
7. to initiate proceedings against Directors and senior management in accordance with the relevant laws;
8. to investigate any irregularities identified in the operation of the Company; if necessary, to engage professional institutions such as accounting firms and law firms to assist its work at the expense of the Company;
9. other powers as set out in the laws, administrative regulations or the Articles of Association.

Resolutions of the Board of Supervisors shall be passed by more than half of the Supervisors.

FINANCIAL AND ACCOUNTING SYSTEM

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations and the requirements of the relevant state authorities.

The annual results reports, annual reports, interim results reports and interim reports of the Company are prepared in accordance with the relevant laws, administrative regulations, the requirements of the CSRC and the stock exchanges where the Company's [REDACTED] are [REDACTED].

NOTICES

A notice of the Company shall be given in the following manner:

1. by hand;
2. by mail;
3. by electronic means or information carriers such as e-mail, fax;
4. by publishing on the websites designated by the Company and the Hong Kong Stock Exchange, subject to the laws, administrative regulations and the listing rules of the stock exchange where the Company's [REDACTED] are [REDACTED];
5. by way of announcement;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

6. other forms agreed in advance by the Company or the person to be notified or accepted by the person to be notified upon receipt of the notice;
7. other means stipulated by securities regulatory authorities of the place where the Company's [REDACTED] are [REDACTED] or the Articles of Association.

Subject to the securities regulatory rules of the place where the Company's [REDACTED] are [REDACTED] and save as otherwise provided in the Articles of Association, where a notice of the Company is published by way of announcement, the said notice shall be deemed as received by all relevant persons once it is published.

DISSOLUTION AND LIQUIDATION OF THE COMPANY

The Company shall be dissolved for the following reasons:

1. the term of its operations as is stipulated in the Articles of Association has expired or events of dissolution specified in the Articles of Association have occurred;
2. the shareholders' general meeting resolves to dissolve the Company;
3. dissolution is necessary due to merger or division of the Company;
4. the Company's business licence is revoked, the Company is ordered to close down or be revoked in accordance with the law;
5. Where the Company encounters serious difficulties in its operation and management and its continuous existence will cause significant losses to the interests of shareholders, and such difficulties cannot be resolved through other means, shareholders holding more than 10% of the voting rights of all shareholders of the Company may request the People's Court to dissolve the Company.

Where the Company is dissolved pursuant to items 1, 2, 4 and 5 above, a liquidation committee shall be established and the liquidation shall commence within 15 days after the occurrence of the cause of dissolution. The liquidation committee shall be composed of Directors or persons determined by the shareholders' general meeting. If a liquidation committee is not established within the time limit, the creditors may apply to the People's Court to designate relevant personnel to form a liquidation committee to carry out liquidation.

The liquidation committee shall notify creditors within 10 days from the date of its establishment.

If the liquidation committee discovers that the Company's assets are insufficient to repay its debts after cleaning up the Company's assets and preparing a balance sheet and an inventory of assets, it shall apply to the People's Court for a declaration of insolvency in accordance with the law.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report which shall be submitted to the shareholders' general meeting or the People's Court for confirmation, and shall submit the same to the company registration authority, apply for cancellation of the Company's registration, and publish an announcement on the termination of the Company.

AMENDMENTS TO THE ARTICLES

The Company shall amend the Articles of Association in any of the following circumstances:

1. After the amendments are made to the Company Law or relevant laws, administrative regulations and securities regulatory rules of the place where the [REDACTED] of the Company are [REDACTED], the provisions of the Articles of Association are in conflict with the amended laws, administrative regulations and securities regulatory rules of the place where the [REDACTED] of the Company are [REDACTED];
2. there is a change in the Company's situation, which is inconsistent with the matters recorded in the Articles of Association;
3. the shareholders' general meeting decides to amend the Articles of Association.

The amendments to the Articles of Association adopted by the shareholders' general meeting shall be submitted to the competent authorities for approval if they are subject to approval by the competent authorities. If there is any change relating to the registered particulars of the Company, application shall be made for registration of the changes in accordance with the laws.

APPENDIX VI

PROPERTY VALUATION REPORT

The following is the full text of a letter, summary of valuations and valuation report prepared for the purpose of incorporation in this document received from Cushman & Wakefield Limited, an independent property valuer, in connection with the valuation of the properties held by the Group as at 31 March 2023. Unless otherwise defined, terms used in this Appendix shall have the same meanings as those set out in this document.



27/F
One Island East,
Taikoo Place
18 Westlands Road
Quarry Bay
Hong Kong

[●] 2023

The Directors
Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
No. 666 Xinhua Avenue
Chengdu Cross-Strait Science and Technology Industry
Development Park
Wenjiang District, Chengdu
Sichuan Province
The People's Republic of China

Dear Sirs,

INSTRUCTIONS, PURPOSE AND DATE OF VALUATION

In accordance with your instructions for us to value the properties held by Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (referred to as the “Company”) and its subsidiaries (hereinafter together referred to as the “Group”) have interests in the People's Republic of China (the “PRC”) (as more particularly described in the valuation report), we confirm that we have inspected the properties, made relevant enquiries and obtained such further information as we consider necessary to provide you with our opinion of the values of such properties as at 31 March 2023 (the “Valuation Date”).

DEFINITION OF MARKET VALUE

Our valuation of each of the properties represents its market value which in accordance with the HKIS Valuation Standards 2020 published by The Hong Kong Institute of Surveyors (“HKIS”) is defined as “the estimated amount for which an asset or liability should exchange on the valuation date between a willing buyer and a willing seller in an arm's length transaction, after proper marketing and where the parties had each acted knowledgeably, prudently and without compulsion”.

APPENDIX VI

PROPERTY VALUATION REPORT

VALUATION BASIS AND ASSUMPTIONS

We confirm that our valuations comply with the requirements set out in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities published by The Stock Exchange of the Hong Kong Limited, and the HKIS Valuation Standards 2020 issued by the HKIS.

Our valuation excludes an estimated price inflated or deflated by special terms or circumstances such as atypical financing, sale and leaseback arrangement, special considerations or concessions granted by anyone associated with the sale, or any element of value available only to a specific owner or purchaser.

In the course of our valuation of the properties in the PRC, we have assumed that, unless otherwise stated, the transferable land use rights of the properties for their respective terms at nominal annual land use fees have been granted and that any premium payable has already been fully paid. We have relied on the information and advice given by the Group and its PRC legal adviser, King & Wood Mallesons, regarding the title to each of the properties and the interests of the Group in the properties. In valuing the properties, we have assumed that the Group has an enforceable title to the properties and has free and uninterrupted rights to use, occupy or assign the properties for the whole of the respective unexpired land use term as granted.

In respect of the properties situated in the PRC, the status of titles and grant of major certificates approvals and licences, in accordance with the information provided by the Group are set out in the notes of the respective valuation report.

No allowance has been made in our valuations for any charges, mortgages or amounts owing on the properties nor for any expenses or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the properties are free from encumbrances, restrictions and outgoings of an onerous nature which could affect their values.

METHOD OF VALUATION

In valuing the properties which are held by the Group under development in the PRC, we have valued the properties on the basis that they will be developed and completed in accordance with the Group’s latest development proposals provided to us (if any). We have assumed that all consents, approvals and licences from relevant government authorities for the development proposals have been obtained without onerous conditions or delays. We have also assumed that the design and construction of the development are in compliance with the local planning regulations and have been approved by the relevant authorities. In arriving at our opinion of value, we have adopted the Depreciated Replacement Cost (“DRC”) Method to assess the “Market Value when completed” and have taken into account the expended construction costs and the costs that will be expended to complete the development to reflect the quality of the completed development.

APPENDIX VI

PROPERTY VALUATION REPORT

We have used the DRC Method to assess the completed value due to the special nature of buildings since there is no readily identifiable market sale comparable and the buildings valued by comparable market transactions. The DRC Method requires a valuation of the market value of the land in its existing use and an estimate of the new replacement cost of the buildings and structures from which deductions are then made to allow for the age, condition and functional obsolescence. The DRC Method generally furnishes the most reliable indication of value of property in the absence of a known market based on comparable sales. In arriving at our opinion of the market value of the land, we have valued the properties by Market Comparison Method by making reference to the comparable sale evidence in the relevant locality. The DRC is subject to adequate potential profitability of the business.

SOURCE OF INFORMATION

We have been provided by the Group with extracts of documents in relation to the titles to the properties. However, we have not inspected the original documents to ascertain any amendments which may not appear on the copies handed to us.

In the course of our valuations, we have relied to a very considerable extent on the information given to us by the Group in respect of the properties in the PRC and have accepted advice given by the Group on such matters as planning approvals or statutory notices, easements, tenure, identification of land and buildings, completion date of buildings, number of car parking spaces, particulars of occupancy, site and floor areas, total construction cost and expended construction cost as at Valuation Date, interest attributable to the Group and all other relevant matters.

Dimensions, measurements and areas included in the valuation report are based on information provided to us and are therefore only approximations. We have had no reason to doubt the truth and accuracy of the information provided to us by the Group which is material to the valuations. We were also advised by the Group that no material facts have been omitted from the information provided.

TITLE INVESTIGATION

We have been provided with extracts of documents relating to the titles of the properties in the PRC, but no searches have been made in respect of the properties. We have not searched the original documents to verify ownership or to ascertain any amendment which may not appear on the copies handed to us. We are also unable to ascertain the title of the properties in the PRC and we have therefore relied on the advice given by the Group and its PRC legal adviser regarding the Group's interests in the PRC properties.

APPENDIX VI

PROPERTY VALUATION REPORT

SITE INSPECTION

Our valuer, Ms. Shona Yue with 6 years of property valuation experience, has inspected the exterior and, whenever possible, the interior of the properties in January 2022. However, we have not carried out investigation on site to determine the suitability of the soil conditions and the services etc. for any future development. Our valuation is prepared on the assumption that these aspects are satisfactory and that no extraordinary costs or delays will be incurred during the construction period. No structural survey has been made, but in the course of our inspection, we did not note any serious defects. We are not, however, able to report that the properties are free of rot, infestation or any other structural defects. No tests were carried out to any of the services. Unless otherwise stated, we have not been able to carry out on-site measurements to verify the site and floor areas of the properties and we have assumed that the area shown on the documents handed to us are correct.

CURRENCY

Unless otherwise stated, all money amounts indicated herein our valuations are in Renminbi ("RMB"), which is the official currency of the PRC.

We enclose herewith a summary of our valuations and our valuation report.

Yours faithfully,
for and on behalf of
Cushman & Wakefield Limited
Grace S.M. Lam
MHKIS, MRICS, RPS (GP)
Senior Director
Valuation & Advisory Services, Greater China

Note: Ms. Grace S.M. Lam is a Member of the Royal Institution of Chartered Surveyors, a Member of the Hong Kong Institute of Surveyors and a Registered Professional Surveyor (General Practice). Ms. Lam has over 30 years of experience in the professional property valuation and advisory services in the Greater China region and various overseas countries. Ms. Lam has sufficient current knowledge of the market, and the skills and understanding to undertake the valuations competently.

APPENDIX VI

PROPERTY VALUATION REPORT

SUMMARY OF VALUATIONS

Properties held by the Group under development in the PRC

Property	Market value in existing state as at 31 March 2023 (RMB)	Interest attributable to the Group (%)	Market value in existing state attributable to the Group as at 31 March 2023 (RMB)
<p>1. Industrial complex under construction at Tianfujiayuan Community, Wenjiang District, Chengdu City, Sichuan Province, the PRC.</p> <p>中國四川省成都市 溫江區天府家園社區 工業廠房的在建工程</p>	271,300,000	100	271,300,000
<p>2. Industrial complex under construction at Groups 6, 7, 8 and 15 of Qingtai Community and Group 4 of Xinba Village, Tianfu Street Office, Wenjiang District, Chengdu City, Sichuan Province, the PRC.</p> <p>中國四川省成都市 溫江區天府街辦青泰社區6、 7、8、15組,新壩村4組 工業廠房的在建工程</p>	120,400,000	100	120,400,000
Total:	391,700,000		391,700,000

APPENDIX VI

PROPERTY VALUATION REPORT

VALUATION REPORT

Properties held by the Group under development in the PRC

Property	Description and tenure	Particulars of occupancy	Market Value in existing state as at 31 March 2023																																	
1. Industrial complex under construction at Tianfujiayuan Community, Wenjiang District, Chengdu City, Sichuan Province, the PRC.	<p>The property comprises nine under-construction buildings in an industrial complex which is developed on a parcel of industrial land with a site area of approximately 63,943.94 sq.m.</p> <p>The property is scheduled to be completed in 2023.</p>	As at the Valuation Date, the property was under development.	RMB271,300,000																																	
中國四川省成都市溫江區天府家園社區工業廠房的在建工程	<p>Upon completion, the property comprises a 4-storey ADC Building, a 4-storey building, four 2-storey warehouses and three 1-storey warehouses with a total gross floor area of approximately 39,079.62 sq.m. with details as follows:</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Building</th> <th>No. of storey</th> <th>Gross Floor Area (sq.m.)</th> </tr> </thead> <tbody> <tr> <td>ADC Building</td> <td>4-storey</td> <td>24,843.46</td> </tr> <tr> <td>Building</td> <td>4-storey</td> <td>9,526.00</td> </tr> <tr> <td>Warehouse</td> <td>2-storey</td> <td>3,467.00</td> </tr> <tr> <td>Warehouse</td> <td>1-storey</td> <td>468.00</td> </tr> <tr> <td>Warehouse</td> <td>2-storey</td> <td>106.70</td> </tr> <tr> <td>Warehouse</td> <td>2-storey</td> <td>125.46</td> </tr> <tr> <td>Warehouse</td> <td>2-storey</td> <td>413.00</td> </tr> <tr> <td>Warehouse</td> <td>1-storey</td> <td>85.00</td> </tr> <tr> <td>Warehouse</td> <td>1-storey</td> <td>45.00</td> </tr> <tr> <td>Total</td> <td></td> <td><u>39,079.62</u></td> </tr> </tbody> </table>	Building	No. of storey	Gross Floor Area (sq.m.)	ADC Building	4-storey	24,843.46	Building	4-storey	9,526.00	Warehouse	2-storey	3,467.00	Warehouse	1-storey	468.00	Warehouse	2-storey	106.70	Warehouse	2-storey	125.46	Warehouse	2-storey	413.00	Warehouse	1-storey	85.00	Warehouse	1-storey	45.00	Total		<u>39,079.62</u>		<p>(RENMINBI TWO HUNDRED SEVENTY ONE MILLION THREE HUNDRED THOUSAND)</p> <p>(100% interest attributable to the Group: RMB271,300,000)</p>
Building	No. of storey	Gross Floor Area (sq.m.)																																		
ADC Building	4-storey	24,843.46																																		
Building	4-storey	9,526.00																																		
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Warehouse	1-storey	85.00																																		
Warehouse	1-storey	45.00																																		
Total		<u>39,079.62</u>																																		
	<p>The property is held with land use rights for a term due to expire on 9 March 2067 for industrial use.</p>																																			

APPENDIX VI

PROPERTY VALUATION REPORT

Notes:–

- (1) According to the State-owned Land Use Rights Certificate, the land use rights of the property with a site area of 63,943.94 sq.m. have been vested in 四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.) for industrial use with details as follows:

Certificate No.	Date of issue	Land use	Expiry date of land use term	Site area (sq.m.)
(2020) 0052569	17 September 2020	Industrial	9 March 2067	63,943.94

- (2) According to Planning Permit for Construction Land Use No. 510115201920556 dated 25 October 2019, the land of construction use with a site area of 63,943.94 sq.m. is in compliance with the urban planning requirements and has been approved.
- (3) According to Planning Permit for Construction Works No. 510115201930858 dated 28 October 2019, the construction works with a total planned gross floor area of 39,079.62 sq.m. are in compliance with the urban planning requirements and have been approved.
- (4) According to Permit for Commencement of Construction Works No. 510115202005221101 dated 22 May 2020, the construction works with a total planned gross floor area of 39,041.77 sq.m. are in compliance with the requirements for works commencement and have been permitted.
- (5) As advised by the Group, the total expended construction cost for the property as at Valuation Date was approximately RMB228,400,445 whilst the outstanding construction cost for completion of the property as at Valuation Date was approximately RMB38,419,836. We have taken into account such amount in our valuation.
- (6) The market value of the proposed development when completed is estimated approximately at RMB309,700,000.
- (7) According to Business Licence dated 9 April 2021, 四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.) was established on 26 November 2016 as a limited company with a registered capital of RMB116,050,609.
- (8) We have been provided with a Legal Opinion on the property prepared by the Group’s PRC legal adviser, King & Wood Mallesons, which contains, among other things, the following information:–
- (i) The State-owned Land Use Rights Certificate of the property is legal, valid and enforceable under the PRC laws;
 - (ii) The land use rights and building ownership of the property have been vested in 四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.);
 - (iii) 四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.) is the sole legal land user of the property and has obtained the relevant certificates and approval from the government in respect of the construction of the property; and
 - (iv) 四川科倫博泰生物醫藥股份有限公司 (Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.) has the right to freely occupy, use, lease, transfer, mortgage and dispose of the land use rights and building ownership of the property.

- (9) The status of the title and grant of major approvals and licences in accordance with the information provided to us are as follows:–

State-owned Land Use Rights Certificate	Yes
Planning Permit for Construction of Land Use	Yes
Planning Permit for Construction Works	Yes
Permits for Commencement of Construction Works	Yes
Business Licence	Yes

APPENDIX VI

PROPERTY VALUATION REPORT

VALUATION REPORT

Property	Description and tenure	Particulars of occupancy	Market Value in existing state as at 31 March 2023
2. Industrial complex under construction at Groups 6, 7, 8 and 15 of Qingtai Community and Group 4 of Xinba Village, Tianfu Street Office, Wenjiang District, Chengdu City, Sichuan Province, the PRC. 中國四川省成都市溫江區天府街辦青泰社區6、7、8、15組,新壩村4組工業廠房的在建工程	The property comprises two under construction buildings in an industrial complex which is developed on a parcel of industrial land with a site area of approximately 68,397.83 sq.m. The property is scheduled to be completed in 2023. Upon completion, the property comprises a 4-storey building and a 1-storey warehouse with a total gross floor area of approximately 23,139.89 sq.m. with details as follows:	As at the Valuation Date, the property was under development.	RMB120,400,000 (RENMINBI ONE HUNDRED TWENTY MILLION FOUR HUNDRED THOUSAND) (100% interest attributable to the Group: RMB120,400,000)

Building	No. of storey	Gross Floor Area (sq.m.)
Building	4-storey	23,094.89
Warehouse	1-storey	45.00
Total		<u>23,139.89</u>

The property is held with land use rights for a term due to expire on 4 January 2067 for industrial use.

Notes:-

- (1) According to the State-owned Land Use Rights Certificate, the land use rights of the property with a site area of 68,397.83 sq.m. have been vested in 四川科納斯製藥有限公司 (Sichuan Konas Pharmaceutical Co., Ltd.) for industrial use with details as follows:-

Certificate No.	Date of issue	Land use	Expiry date of land use term	Site area (sq.m.)
(2018) 0030607	30 May 2018	Industrial	4 January 2067	68,397.83

- (2) According to Planning Permit for Construction Land Use No. 510115201720052 dated 4 August 2017, the land of the construction use with a site area of 68,397.83 sq.m. are in compliance with the urban planning requirements and have been approved.
- (3) According to Planning Permit for Construction Works No. 510115201930835 dated 22 October 2019, the construction works with a total planned gross floor area of 23,139.89 sq.m. are in compliance with the urban planning requirements and have been approved.

APPENDIX VI

PROPERTY VALUATION REPORT

- (4) According to Permit for Commencement of Construction Works No. 510115202001151701 dated 10 April 2020, the construction works with a total planned gross floor area of 23,139.89 sq.m. are in compliance with the requirements for works commencement and have been permitted.
- (5) As advised by the Group, the total expended construction cost for the property as at Valuation Date was approximately RMB74,593,140 whilst the outstanding construction cost for completion of the property as at Valuation Date was approximately RMB4,855,458. We have taken into account such amount in our valuation.
- (6) The market value of the proposed development when completed is estimated approximately at RMB125,200,000.
- (7) According to Business Licence dated 20 January 2020, 四川科納斯製藥有限公司 (Sichuan Konas Pharmaceutical Co., Ltd.) was established on 30 September 2016 as a limited company with a registered capital of RMB4,000,000.
- (8) We have been provided with a Legal Opinion on the property prepared by the Group's PRC legal adviser, King & Wood Mallesons, which contains, among other things, the following information:–
- (i) The State-owned Land Use Rights Certificate of the property is legal, valid and enforceable under the PRC laws;
 - (ii) The land use rights and building ownership of the property have been vested in 四川科納斯製藥有限公司 (Sichuan Konas Pharmaceutical Co., Ltd.);
 - (iii) 四川科納斯製藥有限公司 (Sichuan Konas Pharmaceutical Co., Ltd.) is the sole legal land user of the property and has obtained the relevant certificates and approval from the government in respect of the construction of the property; and
 - (iv) 四川科納斯製藥有限公司 (Sichuan Konas Pharmaceutical Co., Ltd.) has the right to freely occupy, use, lease, transfer, mortgage and dispose of the land use rights and building ownership of the property.
- (9) The status of the title and grant of major approvals and licences in accordance with the information provided to us are as follows:–

State-owned Land Use Rights Certificate	Yes
Planning Permit for Construction of Land Use	Yes
Planning Permit for Construction Works	Yes
Permits for Commencement of Construction Works	Yes
Business Licence	Yes

APPENDIX VII STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was established as a joint stock limited liability company in the PRC on November 22, 2016.

As of the date of this document, our Company’s registered office and head office is located at No. 666 Xinhua Avenue, Chengdu Cross-Strait Science and Technology Industry Development Park, Wenjiang District, Chengdu, Sichuan Province, PRC. Our Company has established a principal place of business in Hong Kong at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong and has been registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on January 26, 2023 with the Registrar of Companies in Hong Kong. Ms. FUNG Wai Sum (馮慧森), one of our joint company secretaries, has been appointed as the authorized representative of our Company for the acceptance of service of process in Hong Kong. The address for service of process is the same as our principal place of business in Hong Kong.

Our Company has applied for the conversion of Domestic Shares and Unlisted Foreign Shares into H Shares, which involves 19,620,539 Domestic Shares and 18,623,632 Unlisted Foreign Shares. The conversion of Domestic Shares and Unlisted Foreign Shares into H Shares has been approved by the CSRC on March 30, 2023.

As our Company was established in the PRC, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. A summary of the relevant provisions of our Articles of Association is set out in “Appendix V – Summary of Articles of Association.” A summary of certain relevant aspects of the laws and regulations of the PRC is set out in “Appendix IV – Summary of Principal Laws and Regulation.”

2. Changes in Share Capital of Our Company

As of the date of our incorporation, our registered share capital was RMB100.0 million divided into 100,000,000 Shares with a nominal value of RMB1.00 each.

The following sets out the changes in the issue share capital of our Company during the two years immediately preceding the date of this document:

On March 22, 2021, the registered share capital of the Company was increased from RMB104.2 million to RMB116,050,609 by way of share subscription by our Series A Investors. Please see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 3. Series A Financing” for details.

On January 3, 2023, the registered share capital of the Company was increased from RMB116,050,609 to RMB193,382,499 by way of share subscription by Kelun Pharmaceutical and our Series B Investors. Please see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing” for details.

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

Upon completion of the [REDACTED] and conversion of Domestic Shares and Unlisted Foreign Shares into H Shares, without taking into account any H Shares which may be [REDACTED] pursuant to the [REDACTED], our registered share capital will be increased to RMB[REDACTED], comprising 149,589,850 Domestic Shares, 5,548,478 Unlisted Foreign Shares and [REDACTED] H Shares, representing [REDACTED]%, [REDACTED]% and [REDACTED]% of our registered capital, respectively.

For further details, please see “History and Corporate Structure” of this document. Save as disclosed above, there has been no alteration in the share capital of our Company during the two years immediately preceding the date of this document.

3. Subsidiaries of our Company and Changes in Share Capital of Our Subsidiaries

Details of our subsidiaries are set out in “History and Corporate Structure – Our Subsidiaries” and note 1 to the Accountants’ Report as set out in Appendix I to this document.

Kelun-Biotech Research Center was established as a limited liability company in the PRC on March 30, 2023 with a registered capital of RMB100 million.

Save as disclosed above, there has been no alteration in the share capital of the subsidiaries of our Company within two years immediately preceding the date of this document.

4. Shareholders’ Resolutions

At the extraordinary general meeting of our Company held on February 15, 2023, among other things, the following resolutions were passed by the Shareholders:

- (a) the issue by our Company of H Shares of nominal value of RMB1.00 each and such H Shares be [REDACTED] on the Stock Exchange;
- (b) the number of H Shares to be [REDACTED] shall be up to [REDACTED], and the grant of the [REDACTED] in respect of no more than 15% of the number of H Shares issued pursuant to the [REDACTED];
- (c) as approved by the CSRC, upon completion of the [REDACTED], 19,620,539 Domestic Shares and 18,623,632 Unlisted Foreign Shares in aggregate will be converted into H Shares on a one-for-one basis;
- (d) subject to the completion of the [REDACTED], the granting of a general mandate to the Board to allot and issue H Shares at any time within a period up to the date of the conclusion of the next annual general meeting of the Shareholders or the date on which the Shareholders pass a special resolution to revoke or change such mandate, whichever is earlier, upon such terms and conditions and for such purposes and to such persons as the Board in their absolute discretion deem fit, and to make necessary amendments to the Articles of Association, provided that, the number of H Shares to be issued shall not exceed 20% of the number of H Shares in issue as at the [REDACTED];

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- (e) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on [REDACTED], and the Board has been authorized to amend the Articles of Association in accordance with any comments from the Stock Exchange and other relevant regulatory authorities; and
- (f) authorization of the Board and its authorized persons to handle all matters relating to, among other things, the [REDACTED], the issue and [REDACTED] of the H Shares.

5. Reorganization

The Company has not gone through any corporate reorganization for the purpose of the [REDACTED]. For details of history and development of the Company, please refer to “History and Corporate Structure”.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contracts

The following contracts (not being contracts entered into in the ordinary course of business) have been entered into by us or any of our subsidiaries within the two years preceding the date of this document that are or may be material:

- (a) the [REDACTED].

2. Our Intellectual Property Rights

(a) Trademarks

(i) Registered Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Place of Registration	Registration No.	Registered Owner	Class	Expiry Date
1.	舒泰菜	PRC	46761751	the Company	5	2031.01.20
2.	希泰菜	PRC	46761750	the Company	5	2031.01.20
3.	宁泰菜	PRC	46761749	the Company	5	2031.01.20
4.	君泰菜	PRC	46761748	the Company	5	2031.01.20

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No.	Trademark	Place of Registration	Registration No.	Registered Owner	Class	Expiry Date
5.	坤泰菜	PRC	46761747	the Company	5	2031.01.20
6.	嘉泰菜	PRC	46761746	the Company	5	2031.01.20
7.	沛泰菜	PRC	46761745	the Company	5	2031.01.20
8.	朗泰菜	PRC	46761744	the Company	5	2031.01.20
9.	佳泰菜	PRC	46761743	the Company	5	2031.01.20
10.	清泰菜	PRC	46761742	the Company	5	2031.01.20
11.	奇泰菜	PRC	46761741	the Company	5	2031.01.20
12.	科泰菜	PRC	46761740	the Company	5	2031.01.20
13.	达泰来	PRC	46602863	the Company	5	2031.01.13
14.	智泰菜	PRC	46602862	the Company	5	2031.01.13
15.	达泰菜	PRC	46602861	the Company	5	2031.01.13
16.	兴泰菜	PRC	46602860	the Company	5	2031.01.20
17.	坦泰菜	PRC	46602859	the Company	5	2031.01.13
18.	希泰来	PRC	46602858	the Company	5	2031.01.13
19.	坤泰来	PRC	46602857	the Company	5	2031.01.13
20.	嘉泰来	PRC	46602856	the Company	5	2031.01.13
21.	沛泰来	PRC	46602855	the Company	5	2031.01.13
22.	朗泰来	PRC	46602854	the Company	5	2031.01.13

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No.	Trademark	Place of Registration	Registration No.	Registered Owner	Class	Expiry Date
23.	智泰来	PRC	46602853	the Company	5	2031.01.13
24.	佳泰来	PRC	46602852	the Company	5	2031.01.13
25.	利泰来	PRC	46602851	the Company	5	2031.01.13
26.	清泰来	PRC	46602850	the Company	5	2031.01.13
27.	兴泰来	PRC	46602849	the Company	5	2031.01.13
28.	卡泰来	PRC	46602848	the Company	5	2031.01.13
29.	坦泰来	PRC	46602847	the Company	5	2031.01.13
30.	卡泰莱	PRC	46503045	the Company	5	2031.01.06
31.	君泰来	PRC	46503044	the Company	5	2031.01.06
32.	舒泰来	PRC	46503043	the Company	5	2031.01.20
33.	科泰来	PRC	46503042	the Company	5	2031.01.20
34.	科伦博泰	PRC	23225123	the Company	10	2028.03.06
35.	科伦博泰	PRC	23225122	the Company	35	2028.03.06
36.	科伦博泰	PRC	23225121	the Company	5	2028.03.06
37.	科伦博泰	PRC	23225120	the Company	44	2028.03.06
38.	科伦博泰	PRC	23225119	the Company	42	2028.03.06
39.	KELUN-BIOTECH	PRC	23225116	the Company	42	2028.03.06
40.	KELUN-BIOTECH	PRC	23225115	the Company	35	2028.03.06
41.	KELUN-BIOTECH	PRC	23225114	the Company	44	2028.03.06

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No.	Trademark	Place of Registration	Registration No.	Registered Owner	Class	Expiry Date
42.		PRC	23225111	the Company	44	2028.03.06
43.		PRC	23225110	the Company	42	2028.03.06
44.		PRC	23225109	the Company	35	2028.03.06
45.	科纳思	PRC	19152007	the Company	35	2028.03.27
46.	KLUS PHARMA	PRC	19151967	the Company	35	2028.03.27
47.	KLUS PHARMA	PRC	19151958	the Company	10	2028.03.27
48.	科纳思	PRC	19151922	the Company	10	2028.03.27
49.	KLUS PHARMA	PRC	19151812	the Company	5	2028.03.27

(ii) Trademark under application

As of the Latest Practicable Date, we had applied for the registration of the following trademarks, which we consider to be or may be material to our business.

No.	Trademark	Place of Application	Application No.	Registered Owner	Class	Application Date
1.	OptiDC	PRC	69795902	the Company	5	2023.02.24
2.	OptiDC	PRC	69783252	the Company	10	2023.02.24
3.	OptiDC	PRC	69777305	the Company	35	2023.02.24
4.	OptiDC	PRC	69776887	the Company	42	2023.02.24

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No.	Trademark	Place of Application	Application No.	Registered Owner	Class	Application Date
5.	OptiDC	PRC	69774499	the Company	44	2023.02.24

(b) Patents

(i) Registered Patents

As of the Latest Practicable Date, we were the registered owner of and had the right to use the following patents which we consider to be or may be material to our business:

No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
1.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2 抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	PRC	2018112985479	2016.11.22	2036.11.22
2.	The solid form of azetidine derivative and preparation method use thereof (氮雜環丁烷衍生物的固體形式及其製備方法和用途)	the Company	PRC	201880023346X	2018.05.28	2038.05.28
3.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	PRC	2018800695435	2018.12.10	2038.12.10
4.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2 抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	PRC	2015108240648	2015.11.23	2035.11.23
5.	A PDL-1 antibody and pharmaceutical composition and use thereof (一種PDL-1抗體、其藥物組合物及其用途)	the Company	PRC	2017101208477	2017.03.02	2037.03.02
6.	Polyamide compound and use thereof (多醯胺化合物及其用途)	the Company	PRC	2017800468206	2017.09.22	2037.09.22
7.	Azetidine derivatives and preparation method and use thereof (氮雜環丁烷衍生物、其製備方法及用途)	the Company	PRC	2016800593964	2016.12.08	2036.12.08
8.	A PDL-1 antibody and pharmaceutical composition and use thereof (一種PDL-1抗體、其藥物組合物及其用途)	the Company	PRC	2018106479747	2017.03.02	2037.03.02
9.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2 抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	PRC	2016800367605	2016.11.22	2036.11.22

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No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
10.	A PDL-1 antibody and pharmaceutical composition and use thereof (一種PDL-1抗體、其藥物組合物及其用途)	the Company	PRC	2017800021828	2017.03.02	2037.03.02
11.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	PRC	2018112986113	2016.11.22	2036.11.22
12.	Preparation method of conjugates (製備偶聯物的方法)	the Company	PRC	2019100617790	2019.01.23	2039.01.23
13.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Hong Kong	HK1243957	2016.11.22	2036.11.22
14.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Hong Kong	HK1254298	2016.11.22	2036.11.22
15.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	Hong Kong	HK40020572	2018.12.10	2038.12.10
16.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Japan	JP6888871	2016.11.22	2036.11.22
17.	Cytotoxins and conjugates, their uses and methods of preparation (細胞毒素和偶聯物、其用途和製備方法)	the Company	U.S.	US11207420B2	2018.04.12	2038.04.12
18.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Eurasian	EA039757	2016.11.22	2036.11.22
19.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Europe	EP3381469	2016.11.22	2036.11.22
20.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Japan	JP7200454B2	2016.11.22	2036.11.22

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(ii) *Pending Patents*

As of the Latest Practicable Date, we had applied for the registration of the following patents which we consider to be or may be material to our business:

No.	Patent Title	Applicant	Place of Registration	Application Number	Application Date
1.	An anti-PD-L1 antibody preparation (一種抗PD-L1抗體製劑)	the Company	PRC	2019111900374	2019.11.28
2.	An of intermediate compound and preparation method therefor, and solid phase synthesis method for preparing polypeptide from intermediate compound (一種中間體化合物及其製備方法,及以該中間體化合物製備多肽的固相合成方法)	the Company	PRC	2019800064095	2019.01.28
3.	A purification method of polypeptide (一種多肽的純化方法)	the Company	PRC	2019800192638	2019.05.05
4.	A use of anti-programmed death ligand-1 (pd-l1) antibody for anti-tumor (抗程序性死亡配體-1(PD-L1)抗體的抗腫瘤用途)	the Company	PRC	2019800591110	2019.09.19
5.	Pharmaceutical composition comprising polypeptide compound, preparation method therefor and use thereof (含有多肽類化合物的藥物組合物及其製備方法和用途)	the Company	PRC	2019800603438	2019.11.08
6.	An antibody and use thereof (一種抗體及其用途)	the Company	PRC	2019800764745	2019.12.19
7.	Oral pharmaceutical composition with azetidine derivative as active ingredient, preparation method and use thereof (以氮雜環丁烷衍生物為活性成分的口服藥物組合物、其製備方法及用途)	the Company	PRC	2020800074009	2020.02.20
8.	Heterocyclic compound, pharmaceutical composition the same and preparation method and use thereof (雜環化合物、包含其的藥物組合物及其製備方法和用途)	the Company	PRC	2020800099542	2020.02.11
9.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	PRC	2021111104339	2018-12-10

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No.	Patent Title	Applicant	Place of Registration	Application Number	Application Date
10.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	PRC	2021111108310	2018.12.10
11.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	PRC	2021111137008	2018.12.10
12.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	PRC	2021111145127	2018.12.10
13.	Salt and crystal of a pyrimidine compound and their preparation method (一種嘧啶類化合物的鹽和晶型及其製備方法)	the Company	PRC	2021800388570	2021.7.23
14.	Cytotoxins and conjugates, their uses and methods of preparation (細胞毒素和偶聯物、其用途和製備方法)	the Company	PRC	2018800125291	2018.4.12
15.	Preparation method of conjugates (製備偶聯物的方法)	the Company	PRC	2019800060944	2019.1.23
16.	Cytotoxic agents and conjugates, preparation method and uses thereof (細胞毒性劑及其偶聯物、其製備方法及用途)	the Company	PRC	2019800063961	2019.1.25
17.	Use of anti-HER2 antibody-drug conjugates in the treatment of cancer (抗HER2抗體-藥物偶聯物在治療癌症中的用途)	the Company	PRC	2019800186355	2019.04.30
18.	Camptothecin derivatives and their water-soluble prodrugs, pharmaceutical compositions containing them, their preparation methods and uses (喜樹碱衍生物及其水溶性前藥、包含其的藥物組合物及其製備方法和用途)	the Company	PRC	2020800065387	2020.01.16
19.	Antibody drug conjugate and its preparation method and use (抗體藥物綴合物及其製備方法和用途)	the Company	PRC	2021800326201	2021.05.12
20.	Bioactive conjugate, preparation method therefor and use thereof (生物活性物偶聯物及其製備方法和用途)	the Company	U.S.	US16758980	2018.12.10
21.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Canada	CA3000763	2016.11.22

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No.	Patent Title	Applicant	Place of Registration	Application Number	Application Date
22.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	Korea	KR1020177036761	2016.11.22
23.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	U.S.	US15765685	2016.11.22
24.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	U.S.	US17169087	2016.11.22
25.	Anti-ErbB2 antibody-drug conjugate and its composition, preparation method and application (抗ErbB2抗體-藥物偶聯物及其組合物、製備方法和應用)	the Company	U.S.	US17471653	2016.11.22
26.	Use of anti-HER2 antibody-drug conjugates in the treatment of cancer (抗HER2抗體-藥物偶聯物在治療癌症中的用途)	the Company	U.S.	US16979251	2019.04.30
27.	Method and use of antibody drug conjugate in cancer treatment (抗體藥物偶聯物治療癌症的方法及用途)	the Company	Patent Cooperation Treaty (PCT)	PCTCN2022089836	2022.04.28
28.	Use of anti-HER2 antibody-drug conjugates in the treatment of cancer (抗HER2抗體-藥物偶聯物在治療癌症中的用途)	the Company	Hong Kong	HK620210234154	2019.04.30
29.	Cytotoxins and conjugates, their uses and methods of preparation (細胞毒素和偶聯物、其用途和製備方法)	the Company	Europe	EP187878053	2018.04.12
30.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	Canada	CA3080236	2018.12.10
31.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	Europe	EP188886238	2018.12.10
32.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	Japan	JP2020521429	2018.12.10

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No.	Patent Title	Applicant	Place of Registration	Application Number	Application Date
33.	Biologically active substance conjugate and its preparation method and use (生物活性物偶聯物及其製備方法和用途)	the Company	Korea	KR1020207010986	2018.12.10
34.	Use of medicament in treatment of tumor disease (藥物在治療腫瘤疾病中的應用)	the Company	Patent Cooperation Treaty (PCT)	WO2022228497A1	2022.11.03
35.	A method for improving the quality of antibody drug coupling product (一種提高抗體藥物偶聯物產品質量的方法)	the Company	Patent Cooperation Treaty (PCT)	PCTCN2022113869	2022.08.22

(c) Copyrights

As of the Latest Practicable Date, we have registered the following copyright that we consider to be or may be material to our business:

No.	Name	Registered Owner	Type	Registration Number	Registration Date
1.	The logos of KEBIOUS and BIOTECH	the Company	Artistic work	國作登字-2020-F-00028611	2020.12.28

(d) Domain Names

As of the Latest Practicable Date, we have registered the following domain name that we consider to be or may be material to our business:

No.	Domain Name	Registrant	Expiry Date
1.	kelun-biotech.com	the Company	2028.05.25

Save as disclosed above, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our business.

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C. FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Directors, Supervisors and Chief Executive

(i) Disclosure of Interests – Interests and short positions of the Directors, Supervisors and chief executive of our Company in the Shares, underlying Shares or debentures of our Company and our associated corporations

Immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), the interests or short positions of our Directors, Supervisors and chief executives in the Shares, underlying Shares and debentures of our Company and its associated corporations, within the meaning of Part XV of the SFO, which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he/she is taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Companies contained in the Listing Rules (for this purpose, the relevant provisions of the SFO will be interpreted as if they apply to the Supervisors), will be as follows:

Name	Position	Nature of interest	Number and description of Shares	Appropriate percentage of interest in our Company
Mr. LIU Gexin (劉革新)	Chairman of the Board and non-executive Director	Interest in a controlled corporation	136,555,685 Domestic Shares	[REDACTED]%
			9,000,000 H Shares	[REDACTED]%
Dr. WANG Jingyi (王晶翼)	Executive Director	Beneficial Owner	2,850,000 Domestic Shares	[REDACTED]%
			2,850,000 H shares	[REDACTED]%

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Save as disclosed above, as of the Latest Practicable Date, none of the Directors, Supervisors or chief executive or their respective spouses and children under 18 years of age had been granted by the Company or had exercised any rights to subscribe for shares or debentures of the Company or any of its associated corporations.

(ii) Particulars of service agreements

Pursuant to Rules 19A.54 and 19A.55 of the Listing Rules, our Company [has entered into] a service agreement with each of the Directors and Supervisors which contains provisions in relation to, among other things, compliance of relevant laws and regulations, observation of the Articles of Association and provisions on arbitration.

The principal particulars of these service agreements are: (a) each of the agreements is for a term of three years following his/her respective appointment date; and (b) each of the agreements is subject to termination in accordance with their respective terms. The service agreements may be renewed in accordance with our Articles of Association and the applicable rules.

Save as disclosed above, our Company has not entered, and does not propose to enter, into any service contracts with any of the Directors or Supervisors in their respective capacities as Directors/Supervisors (other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation)).

(iii) Directors' and Supervisors' remuneration

For the years ended December 31, 2021 and 2022, the total amount paid by us for payments of emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) to Directors were approximately RMB13.1 million and RMB7.9 million, respectively. For remuneration details of all Directors during the Track Record Period, please refer to Note 8 to the Accountants' Report as set out in Appendix I to this document.

For the years ended December 31, 2021 and 2022, the total amount paid by us for payments of emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) to Supervisors were RMB2.2 million and RMB4.7 million, respectively.

Based on the arrangements in force as of the Latest Practicable Date, it is estimated that the total remuneration paid to the Directors and Supervisors for the year ending December 31, 2023 will be approximately RMB16.3 million.

During the Track Record Period, no remuneration was paid by us nor receivable by Directors, Supervisors or the five highest remunerated individuals as incentives for joining or as rewards upon joining our Company. During the Track Record Period, no remuneration was paid by us nor receivable by Directors, past Directors, Supervisors, past Supervisors or the five highest remunerated individuals as compensation for leaving positions relating to management affairs in any subsidiary of the Company.

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During the Track Record Period, none of our Directors have waived any remuneration. Save as disclosed above, during the Track Record Period, no other amounts shall be paid or payable by us or any of our subsidiaries to the Directors or the five highest remunerated individuals.

Save as disclosed above and indirect shareholding interest our Directors and Supervisors held through our Employee Incentive Plan, no Director or Supervisor is entitled to receive other special benefits from the Company.

2. Substantial Shareholders

(i) Interests in the Shares of our Company

For information on the persons (other than our Directors, Supervisors or chief executive of our Company) who will, immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), having or be deemed or taken to have beneficial interests or short position in our Shares or underlying Shares which would fall to be disclosed to our Company under the provisions of 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 10% or more of the issued voting shares of any other member of our Company, see “Substantial Shareholders” of this document.

Save as disclosed in the section headed “Substantial Shareholders” in this document, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), having or be deemed or taken to the beneficial interests or short position in our Shares or underlying Shares which would fall to be disclosed to our Company under the provisions of 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 10% or more of the issued voting shares of any member of our Group or had option in respect of such capital.

(ii) Interests in our Company’s subsidiaries

Immediately following the completion of the [REDACTED], assuming (i) the [REDACTED] has become unconditional and all [REDACTED] have been issued pursuant to the [REDACTED]; and (ii) the [REDACTED] have not been exercised, all member companies of our Group (other than our Company) are wholly owned by our Company. As such, no person (other than our Company) will be interested, directly or indirectly, in 10% or more of share capital with the right to, in any event, vote at the general meeting of any other member (other than our Company) of our Group.

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3. Personal Guarantees

During the Track Record Period, Mr. LIU Gexin provided guarantees in respect of certain bank borrowings by our Group (the "**Guaranteed Loans**"). Please refer to note 21 of the Accountants' Report in Appendix I to this document for further details. As of the Latest Practicable Date, all the outstanding principal amount of the Guaranteed Loans and the accrued interest under the Guaranteed Loans had been fully repaid by us.

Save for the above, no Director or Supervisor has provided personal guarantees for the benefit of the lenders in connection with any banking facilities granted to the Company.

4. Directors' Competing Interests

None of the Company's Directors has any interests in any business which competes or is likely to compete, either directly or indirectly, with the Group's business.

5. Agency Fees or [REDACTED] Paid or Payable

Save as disclosed in "[REDACTED]" section in this document, no commissions, discounts, brokerages or other special terms were granted within the two years preceding the date of this document in connection with the issue or sale of any capital or security of any member of our Group.

6. Disclaimers

Save as disclosed in this document:

- (i) none of our Directors, Supervisors, chief executive or any of the parties listed in "– D. Other Information – 7. Qualification of Experts" is:
 - (a) interested in our promotion, or in any assets which, within the two years immediately preceding the date of this document, have been acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to our Company; or
 - (b) materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to our business;
- (ii) save in connection with the [REDACTED] and the [REDACTED], none of the parties listed in "– E. Other Information – 7. Qualification of Experts":
 - (a) is interested legally or beneficially in any shares in any member of our Group;
or
 - (b) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for any securities in any member of our Group;

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- (iii) none of our Directors or Supervisors or their close associates or any shareholders of our Company who to the knowledge of our Directors owns more than 5% of our issued share capital has any interest in our top five customers or suppliers; and
- (iv) none of our Directors or Supervisors is a director or employee of a company that has an interest in the share capital of our Company which, once the H Shares are [REDACTED] on the Stock Exchange, would have to be disclosed pursuant to Divisions 2 and 3 of Part XV of the SFO.

D. EMPLOYEE INCENTIVE SCHEME

We have approved and adopted the Employee Incentive Scheme in 2016, and further revised it in May 2020 and January 2023, respectively. The Employee Incentive Scheme is not subject to the provisions of Chapter 17 of the Listing Rules as the Employee Incentive Scheme does not involve the grant of new shares or awards by the Company after the [REDACTED].

The Company has established four employee incentive platforms, namely Kelun Huicai, Kelun Huide, Kelun Huineng and Kelun Huizhi (the “**Employee Incentive Platforms**”). As of the Latest Practicable Date, the four Employee Incentive Platforms, in aggregate, held 30,000,000 Shares. For details of our Employee Incentive Platforms, please refer to “History and Corporate Structure – Employee Incentive Platforms” in this document.

Purpose

For the purpose of quickly attracting and recruiting high-end talents, fully mobilizing the enthusiasm of our core employees, ensuring the stability, motivation and long-term of the core R&D personnel’s labor relationships, accelerating the development process of products candidates, encouraging core employees to work hard and aligning their interest with the long-term development of our Company, the Company provides equity incentives for core employees.

Form of the Employee Incentive Scheme

Participants, as partners of the Employee Incentive Platforms which are in the form of limited partnerships, shall subscribe for the capital contribution of the limited partnership interest according to the amount approved by the equity incentive management committee (the “**Equity Incentive Management Committee**”), and make the corresponding payment in accordance with the arrangement of the Equity Incentive Management Committee, thereby indirectly holding the shares of the Company by virtue of their capacity as a limited partner of the relevant Employee Incentive Platform.

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Participants

The participants include the senior management, key technical personnel and other core employees, directors, supervisors or consultants of the Company, Sichuan Konas and KLUS (the “**Participants**”).

The Equity Incentive Management Committee shall determine or adjust the scope of Participants and the incentive shares after considering factors such as the employee’s working years, on-boarding situations, annual appraisal performance, nature of the job, seniority, and sense of corporate identity.

Total Number of the Incentive Shares

Participants shall hold a total of 30,000,000 shares of the Company through the limited partnerships, which means that four limited partnerships serving as the Employee Incentive Platforms shall hold a total of 30,000,000 shares of the Company, corresponding to the capital of the Company of RMB30 million.

Subscription Price of the Incentive Shares

The subscription price of the incentive shares is based on comprehensive consideration of factors and is determined by Equity Incentive Management Committee according to the following principles:

The subscription price for the first batch of Participants to subscribe and pay for the incentive shares in 2017 is RMB1.00 per share, and the price for subsequent batches of Participants to subscribe and pay for the incentive shares is calculated as: $RMB1.00 \times (1 + 6\% \times N)$ (“N” refers to the number of years, “N” is calculated by the calendar year in which such Participants were granted incentive shares for the first time less 2017).

Payment of the Incentive Share Price

Participants must subscribe for the incentive shares in cash, and should ensure that their source of funds is genuine and lawful.

The subscription period of the incentive shares shall be determined by the Equity Incentive Management Committee. Participants shall make the corresponding payment for incentive shares fully and timely. Participants who fail to pay or pay less than the corresponding price as stated in the notice of grant issued by the Equity Incentive Management Committee are deemed to give up the opportunity to subscribe for the incentive shares. The Equity Incentive Management Committee has the right to adjust or revoke the qualifications of Participants, and return the paid principal (without interest).

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Distribution Method of the Incentive Shares

- (1) **Original distribution:** Based on the factors such as the current working years and previous performance, the Equity Incentive Management Committee will determine the scope of Participants and the number of the incentive shares. Unless approved by the Equity Incentive Management Committee, the cumulative incentive shares held by a single natural person through this method shall not exceed 0.5% of the total incentive shares. The employees who have obtained the original distribution shares are regarded as the first batch of Participants, and shall make the payment in installments and are deemed to have obtained the incentive shares at the establishment of the limited partnerships.
- (2) **Annual appraisal distribution:** According to the annual appraisal by the Company and associated subsidiaries, the Equity Incentive Management Committee has the right to decide to add new Participants or increase the number of the incentive shares of existing Participants every year.
- (3) Unless approved by the Equity Incentive Management Committee, the cumulative incentive shares held by a single natural person shall not exceed 1% of the total incentive shares subscribed through the original distribution and annual appraisal distribution.

Distribution Procedures of the Incentive Shares

The Equity Incentive Management Committee is responsible for the distribution of the incentive shares. In general, the distribution procedures are as follows:

- (1) The Equity Incentive Management Committee decides the specific conditions for eligible Participants, the allocation of the incentive shares among different internal departments and divisions, the preliminary grantee list and the number of shares proposed to be granted.
- (2) The management of relevant departments of the Company and its subsidiaries is responsible for formulating departmental allocation plans, selecting the Participants from the lists, determining the number of incentive shares, and submitting the departmental allocation plans to the Equity Incentive Management Committee.
- (3) The Equity Incentive Management Committee is responsible for making the final decisions about the selected Participants and number of the incentive shares to be granted to each selected Participants.
- (4) The selected Participants shall sign relevant legal documents and pay the subscription price in accordance with the arrangement and instructions of the Equity Incentive Management Committee.

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Obligations of Participants

The main obligations of Participants are as follows:

- (1) The incentive shares held by Participants shall be locked up for a period of 4 years from the effective date of the incentive shares grant agreement (the “**Incentive Shares Grant Agreement**”). During the 4-year lock-up period, Participants are not allowed to transfer the incentive shares to any third party, nor use the incentive shares for guarantee or repayment of debts. During the lock-up period, if Participants rescind or terminate the labor or business relationship with the Company or its subsidiaries, Participants shall follow the relevant arrangements to cooperate with the executive partner to go through the relevant procedures for repurchasing their incentive shares. Participants shall voluntarily commit to continuing to hold the incentive shares for more than 1 year after the expiration of the lock-up period.
- (2) Individual income tax arising from withdrawal, holding or transfer of the incentive shares, dividends or other activities shall be borne by Participants themselves.
- (3) Participants are obliged to abide by other relevant administration measures formulated by Kelun Pharmaceutical and the Company at the general meetings, the meetings of board of directors and the meetings of the Equity Incentive Committee.

Arrangements for Participants Resigning during the Lock-up Period

During the lock-up period, if Participants rescind or terminate the labor or service contracts with the Company or its subsidiaries, Participants shall transfer all their incentive shares to the executive partner or its designated third party according to the requirements of the executive partner. Such incentive shares transferred to the executive partner or the designated third party shall be used in accordance with the decision of the Equity Incentive Management Committee.

Overall Repurchase of the Incentive Shares

For the incentive shares held by Participants, Kelun Pharmaceutical or its subsidiaries shall have the right to repurchase relevant incentive shares as a whole according to business needs. Overall repurchase can be done all in one time or in batches.

When conducting the overall repurchase, appropriate methods such as issuing shares to purchase assets, repurchasing in cash, or a combination of these two methods may be adopted. When necessary, an independent third-party financial consultant or valuer could be engaged to assess the fair valuation of the relevant incentive shares.

Adjustment to the Employee Incentive Scheme

When the number of Participants, fundraising methods and incentive methods may raise regulatory concern or affect the long-term development of the Company's overall interests, Kelun Pharmaceutical and the Company have the right to make corresponding adjustments to the effective documents of the Employee Incentive Scheme and other incentive management measures provided that such adjustments comply with the principles of fairness, justice, win-win and order.

Equity Incentive Management Committee

The Equity Incentive Management Committee is responsible for the daily decision-making, management and execution of employee equity incentive matters. The Equity Incentive Management Committee is composed of five members, elected by and responsible to the Board. The Equity Incentive Management Committee is responsible for the following matters:

- (1) handling specific matters such as the selection of Participants, determination of allocated shares, and payment arrangements for the incentive shares in accordance with the basic principles confirmed by Kelun Pharmaceutical's board of directors;
- (2) daily management of agreements and documents related to the Employee Incentive Scheme;
- (3) formulating and revising the terms of reference of the Equity Incentive Management Committee; and
- (4) other matters concerning the Equity Incentive Management Committee.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

Details of the Incentive Shares Granted Under the Employee Incentive Scheme

As of the Latest Practicable Date, awards corresponded to a total of 22,761,250 Shares, representing approximately 75.87% of the total Shares under the Employee Incentive Scheme, have been granted to the Participants. Details of the incentive shares granted to Directors, Supervisors and senior management under the Employee Incentive Scheme are set out below:

Name	Position	Relevant Employee Incentive Platforms	Approximate partnership interests of the Employee Incentive Platforms	Approximate number of shares corresponding to awards held by the Employee Incentive Platforms	Approximate shareholding percentage corresponding to awards in the total number of shares in issue immediately prior to the [REDACTED]
Dr. GE Junyou (葛均友)	Executive Director and general manager	Kelun Huicai	28.00%	2,100,000	1.09%
Mr. FENG Hao (馮昊)	Non-executive Director	Kelun Huicai	5.60%	420,000	0.22%
Mr. LAI Degui (賴德貴)	Chairman of the Board of Supervisors and Supervisor	Kelun Huicai	5.60%	420,000	0.22%
Ms. LIAO Yihong (廖益虹)	Supervisor	Kelun Huicai	2.27%	170,000	0.09%
Dr. SONG Hongmei (宋宏梅)	Supervisor	Kelun Huizhi	6.00%	450,000	0.23%
Ms. YANG Qiuyan (楊秋艷)	Supervisor	Kelun Huineng	4.27%	320,000	0.17%
Dr. QING Yan (卿燕)	Supervisor	Kelun Huicai	5.33%	400,000	0.21%
Mr. FENG Yi (馮毅)	Deputy general manager, chief strategy officer and senior vice president	Kelun Huicai	16.00%	1,200,000	0.62%
Dr. ZHANG Yiwei (張一偉)	Deputy general manager	Kelun Huineng	4.67%	350,000	0.18%
Dr. TAN Xiangyang (譚向陽)	Deputy general manager and chief scientific officer	Kelun Huineng	4.67%	350,000	0.18%
Dr. JIN Xiaoping (金小平)	Deputy general manager and chief medical officer	Kelun Huineng	8.00%	600,000	0.31%
Mr. ZHOU Zejian (周澤劍)	Chief financial officer	Kelun Huide	9.33%	700,000	0.36%

As of the Latest Practicable Date, Kelun Jingchuan, the general partner of each of the Employee Incentive Platforms and a wholly-owned subsidiary of Kelun Pharmaceutical, held a partnership interest corresponded to 150,000 Shares, 1,558,750 Shares, 2,680,000 Shares and 2,850,000 Shares, in each of the four Employee Incentive Platforms, namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide, respectively (the “**Outstanding Awards**”). The Company intends to continue granting the Outstanding Awards to the Participants, including the senior management, key technical personnel and other core employees, directors, supervisors or consultants of the Company, Sichuan Konas and KLUS, pursuant to the terms of the Employee Incentive Scheme.

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E. OTHER INFORMATION

1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries.

2. Litigation

During the Track Record Period and as of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance was known to our Directors to be pending or threatened by or against us, that would have a material adverse effect on our results of operations or financial conditions.

3. Joint Sponsors

The Joint Sponsors have made an application on behalf of our Company to the [REDACTED] Committee of the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares to be converted from [REDACTED] Foreign Shares and the H Shares to be [REDACTED] pursuant to the [REDACTED] (including the additional H Shares which may be issued pursuant to the exercise of the [REDACTED]). All necessary arrangements have been made to enable our H Shares to be admitted into [REDACTED]. The Joint Sponsors satisfy the independence criteria applicable to Sponsors set out in Rule 3A.07 of the Listing Rules.

Each of the Joint Sponsors will be paid by our Company a fee of US\$500,000 to act as a Sponsor to our Company in connection with the [REDACTED].

4. Compliance Advisor

Our Company has appointed First Shanghai Capital Limited as our compliance advisor in compliance with Rule 3A.19 of the Listing Rules.

5. Preliminary Expenses

We have not incurred any material preliminary expenses in relation to the incorporation of our Company.

6. Taxation of holder of H Shares

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty if such sale, purchase and transfer are effected on the H Share register of members of our Company, including in circumstances where such transactions are effected on the Stock Exchange. The current rate of Hong Kong stamp duty for such sale, purchase and transfer is 0.13% of the consideration or, if higher, the fair value of the H Shares being sold or transferred.

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7. Qualification of Experts

The following are the qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given opinions or advice which are contained in this document:

Name	Qualification
Goldman Sachs (Asia) L.L.C.	Licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities under the SFO
CITIC Securities (Hong Kong) Limited	Licensed corporation to conduct Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
King & Wood Mallesons	Legal advisers as to PRC law
Frost & Sullivan	Independent industry consultant
Cushman & Wakefield Limited	Property valuer
KPMG	Certified Public Accountants Public Interest Entity Auditor registered in accordance with the Accounting and Financial Reporting Council Ordinance

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of 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 our Group.

8. Consent of Experts

Each of the experts whose names are set out in paragraph 7 above has given and has not withdrawn its consent to the issue of this document with the inclusion of its report and/or letter and/or legal opinion (as the case may be) and references to its name included herein in the form and context in which it respectively appears.

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9. Promoters

The promoters of our Company are Kelun Pharmaceutical, Kelun Huicai, Kelun Huide, Kelun Huineng and Kelun Huizhi.

Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to the promoters named above in connection with the [REDACTED] and the related transactions described in this document.

10. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance on 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).

11. Binding Effect

This document shall have the effect, if an application is made in pursuance of this document, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of Sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in so far as applicable.

12. No Material Adverse Change

Our Directors confirm that there has been no material adverse change in the financial or trading position or prospects of our Group since December 31, 2022 (being the date to which the latest audited consolidated financial statements of our Group were prepared).

13. Related Party Transactions

Our Group entered into the related party transactions within the two years immediately preceding the date of this Document as mentioned in Note 30 of the Accountants' Report set out in Appendix I to this document.

14. Miscellaneous

(a) Save as disclosed in “History and Corporate Structure”, “Financial Information”, Appendix I, and the section headed “– D. Employee Incentive Scheme” in this Appendix VII, within the two years immediately preceding the date of this document:

- (i) no share or loan capital or debenture of our Company or any of our subsidiaries has been issued or agreed to be issued or is proposed to be issued for cash or as fully or partly paid other than in cash or otherwise;

APPENDIX VII

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- (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option; and

no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries.
- (b) Save as disclosed in "History and Corporate Structure", "Financial Information" Appendix I, and the sections headed "- D. Employee Incentive Scheme" in this Appendix VII:
 - (i) there are no founder, management or deferred shares nor any debentures in our Company or any of our subsidiaries;
 - (ii) there is no arrangement under which future dividends are waived or agreed to be waived;
 - (iii) there are no contracts for hire or hire purchase of plan to or by us for a period of over one year which are substantial in relation to our business;
 - (iv) no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of its subsidiaries by our Company for subscribing or agreeing to subscribe, or procuring or agreeing to procure subscriptions, for any shares in or debentures of our Company or any of our subsidiaries; and
 - (v) there are no outstanding debentures or convertible debt securities of our Company or any of our subsidiaries.
- (c) Save as disclosed in the paragraph headed "- B. Further Information about our Business - 1. Summary of Material Contracts" in this section, none of our Directors or proposed Directors or experts (as named in this document), have any interest, direct or indirect, 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 our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group.
- (d) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document.
- (e) none of our equity and debt securities is presently listed on any stock exchange or traded on any trading system and no such listing or permission to list is being or is proposed to be sought.

**APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the [REDACTED];
- (b) the written consents referred to in “Appendix VII – Statutory and General Information – E. Other Information – 8. Consent of Experts”; and
- (c) a copy of each of the material contracts referred to in “Appendix VII – Statutory and General Information – B. Further Information about Our Business – 1. Summary of Material Contracts.”

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be published on the Stock Exchange’s website at www.hkexnews.hk and our Company’s website at www.kelun-biotech.com during a period of 14 days from the date of this document:

- (a) the Articles of Association of our Company;
- (b) the Accountants’ Report prepared by KPMG, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of our Group for the two years ended December 31, 2021 and December 31, 2022;
- (d) the report on unaudited [REDACTED] financial information of our Group prepared by KPMG, the text of which is set out in Appendix II to this document;
- (e) the legal opinions issued by King & Wood Mallesons, our PRC Legal Advisor, in respect of the general matters and property interests of our Company;
- (f) the industry report prepared by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., the summary of which is set forth in “Industry Overview” in this document;
- (g) the letter, summary of valuations and valuation certificates relating to certain property interests of our Company prepared by Cushman & Wakefield Limited, the texts of which are set out in Appendix VI to this document;
- (h) a copy of each of the PRC Company Law, the PRC Securities Law, together with their unofficial English translations;

**APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF
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- (i) the material contracts referred to in “Appendix VII – Statutory and General Information – B. Further Information about Our Business – 1. Summary of Material Contracts”;
- (j) the written consents referred to in “Appendix VII – Statutory and General Information – E. Other Information – 8. Consent of Experts”; and
- (k) the service contracts and the letters of appointment referred to in “Appendix VII – Statutory and General Information – C. Further Information about Our Directors, Supervisors and Substantial Shareholders – 1. Directors, Supervisors and Chief Executive – (ii) Particulars of service agreements.”